US DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Evaluation of Specimen Readings for Accuracy and Quality Assurance in the Laboratory at the John D. Dingell VA Medical Center in Detroit, Michigan

Healthcare Inspection | **25-01187-244** | **December 8, 2025**

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Executive Summary

The VA Office of Inspector General (OIG) initiated a healthcare inspection on March 6, 2025, at the John D. Dingell VA Medical Center (facility) in Detroit, Michigan, to evaluate allegations regarding inaccurate identification and reporting of laboratory blood test results and a laboratory staff member not passing a required proficiency test in July 2024. The OIG conducted a site visit April 1–3, 2025, and conducted interviews virtually through August 6, 2025.

According to Veterans Health Administration (VHA) Directive 1106, *Pathology and Laboratory Medicine Service,* laboratory directors are responsible for ensuring laboratory operations and services are conducted efficiently and effectively.[1] The directive also mandates that proficiency testing be performed through a Centers for Medicare and Medicaid Services accredited provider, such as the College of American Pathologists (CAP). Laboratory staff are required to process specimens that the testing provider scores and evaluates.[2] To comply with federal regulations, VHA requires laboratory leaders and staff to participate in and report proficiency testing results "for every instrument and method (including backups) used for patient testing."[3] Additionally, when patient safety events occur, VHA Directive 1050.01(1) instructs patient safety managers to validate that actions are taken following a patient safety event to prevent future patient harm.[4]

The OIG substantiated multiple medical technologists reported inaccurate laboratory results for a patient; however, the OIG did not identify adverse clinical outcomes related to these inaccuracies. The OIG also determined laboratory leaders lacked a quality assurance process to ensure the accuracy of results.[5] Further, the OIG substantiated that a supervisor did not pass a College of American Pathologists blood bank proficiency test related to crossmatching in

[1] VHA Directive 1106, *Pathology and Laboratory Medicine Service,* January 24, 2024.

[2] "Laboratory Accreditation Program," College of American Pathologists (CAP), accessed February 12, 2025, https://www.cap.org/laboratory-improvement/accreditation/laboratory-accreditation-program; VHA Directive 1106. VHA requires all VA medical facility laboratories to participate in external Centers for Medicare and Medicaid Services-approved proficiency testing programs approved by the National PLM Quality and Compliance agent. The National PLM Quality and Compliance agent told the OIG that CAP is an approved proficiency testing provider, contracted with the NEO; CAP is an organization of board-certified pathologists that "serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide." "About the College of American Pathologists," CAP, accessed June 10, 2025, https://www.cap.org/about-the-cap.

[3] VHA Directive 1106.

[4] VHA Directive 1050.01(1), *VHA Quality and Patient Safety Programs*, March 24, 2023, amended March 5, 2024.

[5] Laboratory leaders refer to combinations of the laboratory director and manager, as well as the hematology medical director and supervisor.

June 2024, and services were suspended for one week.[6] However, the OIG found that the former laboratory director and manager took corrective actions and completed requirements to resume crossmatch testing services.[7] Moreover, there were no delays or canceled surgeries during the suspension.

Patient Case Summary

The patient was in their seventies, diagnosed with acute myeloid leukemia (AML) in 2022, received chemotherapy treatment throughout 2023, and found to be in remission in early 2024.[8]

In spring 2024, the patient was seen in the facility's emergency department for shortness of breath and diagnosed with pneumonia and heart failure. The patient's complete blood count (CBC) with differential revealed low blood counts and the presence of myeloblasts (blasts) consistent with a relapse of AML requiring a restart of chemotherapy.[9] In early fall 2024, while continuing chemotherapy treatment, the patient presented to the emergency department with difficulty breathing and had a CBC with differential that was reported as having 4 percent blasts. The provider diagnosed the patient with pneumonia and admitted the patient to the facility for treatment (hospital day 1).

Laboratory results entered into the electronic health record (EHR) on hospital days 2 and 3 indicated no blasts. On hospital day 4, the oncologist documented a discussion with a pathologist that a peripheral smear read that day showed "a large number of blasts concerning for relapsed AML."[10] Additional testing results showed blast counts consistent with AML relapse. The oncologist discussed new chemotherapy options with the patient, but the patient would not be a candidate until completing pneumonia treatment with a return to baseline health.

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[6] Crossmatching is "the testing of the compatibility of the bloods of a transfusion donor and a recipient." *Merriam-Webster.com Medical Dictionary*, "crossmatching," accessed May 13, 2025, https://www.merriam-webster.com/medical/crossmatching; CAP is an organization of board-certified pathologists that provides education and support to the practice of pathology and laboratory medicine. "About the College of American Pathologists," College of American Pathologists (CAP), accessed June 10, 2025, https://www.cap.org/about-the-cap.

[7] VHA Directive 1106.

[8] Acute myeloid leukemia is a type of fast-growing blood cancer that originates in the bone marrow and moves into the blood. "About Acute Myeloid Leukemia (AML)," American Cancer Society, accessed April 14, 2025, https://www.cancer.org/content/dam/CRC/PDF/Public/8674.00.pdf.

[9] A CBC measures the number of red blood cells, white blood cells (WBCs), and platelets in the blood, and a CBC with differential details the number of different types of white and immature blood cells present. Cleveland Clinic, "Complete Blood Count (CBC)," accessed May 8, 2025, https://my.clevelandclinic.org/health/diagnostics/4053-complete-blood-count; The presence of myeloblasts, or "blasts," are cells in the early stage of development and can indicate cancer, such as AML. Cleveland Clinic, "Blast Cells," accessed May 9, 2025, https://my.clevelandclinic.org/health/body/blast-cells.

[10] A peripheral smear is a laboratory technique where a thin layer of blood is stained on a glass slide to examine cells under a microscope. MedlinePlus, "Blood Smear," accessed April 28, 2025, https://medlineplus.gov/lab-tests/blood-smear/; Hospital day 4 was a Monday, and the pathologist's peripheral smear reading was from the specimen collected on hospital day 2.

The patient completed treatment for pneumonia and was discharged home on hospital day 14. Seven days later, the hematology supervisor corrected 11 of the patient's blood count differential results spanning from hospital day 1 through hospital day 14.[11] Twelve days after the discharge, a physician readmitted the patient for worsening cough with increased difficulty breathing, and the patient died several days later.

CBC with Differential Results

When a medical technologist analyzes a CBC with differential specimen, and blasts are identified as "new," the technologist is required to notify the ordering provider and send the slide to a pathologist for a secondary review.[12]

The OIG reviewed the patient's manual CBC with differential laboratory studies performed in fall 2024 and found 11 of 13 studies, completed by eight medical technologists, contained inaccurate blast results.[13] Several medical technologists missed the presence of blasts, and therefore did not send the slides to a pathologist for secondary review, or under reported the percentage of blasts in the blood specimens.[14]

The hematology supervisor and laboratory manager became aware of the inaccurate results after a joint patient safety report was submitted in fall 2024.[15] The oncologist told the OIG that the delayed knowledge of the corrected CBC with differential results did not affect the patient's care or outcome.

The OIG asked laboratory leaders about the magnitude of inaccurate results and learned of the belief that medical technologists tend to under report or misidentify blasts. One reason provided was the facility serves a low volume of patients with AML and other conditions where blasts may be present. To address the errors, the hematology supervisor discussed the performance errors in a staff huddle but did not provide individual feedback to the medical technologists regarding the inaccurate readings.

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[11] Hematology is "the study of blood and blood disorders." "Hematology," John Hopkins Medicine, accessed May 6, 2025, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/hematology.

[12] Facility Policy HEM 017 (2.0), *Resulting Sysmex XN-9100 Print-Offs For CBC With Differential*, October 2, 2024. This policy was replaced by Facility Policy HEM 017 (3.0), *Resulting Sysmex XN-9100 Print-Offs for CBC with Differential*, April 2, 2025, and subsequently Facility Policy HEM 017 (4.0), *Resulting Sysmex XN-9100 Print-Offs for CBC with Differential*, April 11, 2025. The HEM 017 (2.0) version of this policy was in effect at the time of the event—the laboratory director told the OIG that "new" blasts refer to blasts that are seen for the first time or reappear after treatment.

[13] A medical technologist reviewing the blood specimen under a microscope to produce results of a CBC with differential is referred to as a *manual differential*.

[14] The term "missed" indicates that blasts were present in the CBC with differential blood specimen but were not recognized by the medical technologist. The term "under reported" means the medical technologist identified blasts in the blood specimen but reported a percentage lower than what was present.

[15] VHA Directive 1050.01(1).

Laboratory Quality Assurance Processes

The OIG found laboratory leaders had not implemented ongoing reviews of medical technologists' accuracy in cell identification, as required, despite knowledge of the technologists' errors in reading specimens.

The hematology supervisor explained that quality assurance review requirements for manual CBC differential results focus on the accurate entry of test results into the EHR, but do not assess the accuracy of cell identification.[16] The OIG concluded that the lack of a quality assurance process to monitor the accuracy of blast identification posed a risk to patient safety.

Laboratory Leaders' Response

The OIG determined that once aware of the inaccurate CBC with differential results in fall 2024, the laboratory manager developed an action plan to change policy and improve staff competencies. During interviews, the laboratory director denied having knowledge of the patient's inaccurate CBC with differential results in fall 2024, or the associated plans for policy change and additional competencies, until receiving notification of the OIG inspection in March 2025.[17]

In April 2025, one month after the being notified of the OIG inspection, the hematology supervisor and laboratory director changed the policy to require pathologists complete a secondary review of specimens with abnormal cells (such as suspicious for blasts).[18] The OIG questioned the laboratory director about the delay in initiating the policy revision and the director stated, "I don't know why it took so long."

However, laboratory leaders did not initiate implementation of the corrective actions until about five months later. Further, neither the patient safety managers nor the laboratory quality management technologist ensured completion of the planned actions as required.[19]

The OIG also found the hematology supervisor created additional competencies; however, the competencies were not completed until almost six months from first awareness of the inaccurate results. Of the 23 hematology medical technologists tested, 7 did not identify the presence of

[16] VHA Directive 1106. The National Pathology and Laboratory Medicine (PLM) Quality and Compliance agent told the OIG that the National Enforcement Office (NEO) does not track hematology quality assurance metrics and Veterans Integrated Service Network staff are not typically involved in laboratory oversight. The NEO is a division under VHA Pathology and Laboratory Medicine and monitors laboratory performance.

[17] The laboratory director also told the OIG that being new to the role in fall 2024 may have been a factor in not having awareness of the inaccurate CBC with differential results and the associated response.

[18] Facility Policy HEM 017 (2.0). Version 3.0 added a requirement for pathologist review if a medical technologist observed suspicious cells on a specimen slide. Facility Policy HEM 017 (3.0), *Resulting Sysmex XN-9100 Print-Offs for CBC with Differential*, April 2, 2025.

[19] VHA Directive 1050.01(1). Patient safety managers should ensure "immediate actions are taken following a patient safety event."

blasts, or did not accurately determine the percentage of blasts present, thus requiring retraining.[20]

The OIG is concerned the delay in completing additional competencies left patient safety risks unmitigated.[21]

Retrospective Facility Reviews

VHA defines high reliability as "exceptional care [that] is consistently delivered for every patient, every time" and is founded on a continuing commitment to prevent harm and improve processes.[22] The OIG found that despite awareness of the CBC with differential inaccuracies, the laboratory director and manager did not ensure comprehensive retrospective reviews to monitor accuracy until after the OIG site visit in spring 2025.

When the laboratory manager became aware of the inaccurate CBC with differential results, the manager checked a "critical" laboratory results list during the two months after the errors for any patients where blasts were identified but did not review actual specimen slides for other patients. No additional patients with inaccurate results were identified.[23] The OIG is concerned that if specimen slides, including those with "normal" results, were not reviewed to determine whether medical technologists' readings were accurate, the laboratory manager could not be sure if blasts were missed for other patients.

The OIG concluded that facility pathologists completed the OIG-requested retrospective review; however, the OIG remains concerned that medical technologists may continue to misread blasts without sustained oversight.

Laboratory Leaders' Corrective Action

The OIG reviewed laboratory policy and procedures and found laboratory leaders did not fully investigate the CBC with differential inaccuracies or track the effectiveness of actions in response to the variance report as required.

Laboratory staff must report all quality and patient safety concerns by submitting a variance report to the section supervisor for immediate investigation. The section supervisor resolves the concern and provides the variance report to the laboratory quality management technologist for

[20] One of the seven technologists was also identified as reporting inaccurate results for the patient in fall 2024.

[21] VHA, *VHA High Reliability Organization (HRO) Reference Guide*, September 2024.

[22] VHA, *VHA High Reliability Organization (HRO) Reference Guide*.

[23] Since critical laboratory results were the trigger for review, the laboratory manager denied reviewing normal results during an interview and stated, "maybe we should change that." The OIG learned from the hematology supervisor that specimen slides are kept up to 60 days. VA Diagnostic Services, "Record and Specimen Retention Guidelines for Pathology and Laboratory Medicine," January 21, 2025 (6.1). The hematology medical director also conducted a review of all peripheral blood smear slides identified by the hematology analyzer to be suspicious for presence of blasts or abnormal cells in the first half of April 2025. The hematology medical director "found no discrepant differentials or missed blasts."

review, who then provides the document to the laboratory manager and director for review and approval. The laboratory Quality Assurance Committee must review variance reports, determine if a more "intensive investigation" is required, and if so, submit a corrective action plan and "follow-up to assess the effectiveness of the action taken."[24]

The OIG reviewed documentation and confirmed the hematology supervisor submitted a variance report regarding the inaccurate results. However, neither the laboratory manager nor director signed the variance report as required.[25]

The OIG made five recommendations to the Facility Director related to feedback to staff, patient safety, laboratory quality management, oversight of manual CBC with differential reads for accuracy, and corrective actions.

VA Comments and OIG Response

The Acting Veterans Integrated Service Network and Facility Directors concurred with the findings and recommendations (see appendixes A and B). The Facility Director submitted action plans to ensure compliance with policies GEN031 (Competency Assessment Policy) and HEM017 (Resulting Sysmex XN-9199 Print-Offs for CBC with Differential). These plans include supervisors reviewing errors and discussing applicable lessons learned with staff, as well as reporting outcomes during monthly quality assurance meetings.

Additionally, the Facility Director outlined steps to ensure the timely resolution of patient safety events. This includes tracking and monitoring service-level corrective action plans through the Quality and Patient Safety service. The Facility Director also informed the OIG of ongoing compliance reviews to verify the use of a protocol for monthly retrospective secondary reviews by pathologists.

[24] Facility Policy GEN007.

[25] Facility Policy GEN007.

Effective July 2025, the quality management technologist began formally reporting analyses of internal errors and corrective actions during monthly quality assurance meetings, in collaboration with the Quality and Patient Safety service. The Facility Director committed to ensuring that all supervisory staff are educated on the role and responsibilities of the quality management technologist.

The OIG will follow up on the planned actions until they are completed.

JULIE KROVIAK, MD
Principal Deputy Assistant Inspector General,
in the role of Acting Assistant Inspector General,
for Healthcare Inspections

Contents

Abbreviations

AML	acute myeloid leukemia
CAP	College of American Pathologists
CBC	complete blood count
EHR	electronic health record
JPSR	joint patient safety report
NEO	National Enforcement Office
OIG	Office of Inspector General
PLM	pathology and laboratory medicine
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
WBC	white blood cell

Introduction

The VA Office of Inspector General (OIG) initiated a healthcare inspection on March 6, 2025, at the John D. Dingell VA Medical Center (facility) in Detroit, Michigan, to evaluate allegations regarding (1) inaccurate identification and reporting of laboratory blood test results that led to an adverse patient outcome, and (2) that laboratory staff "failed" a required proficiency audit in July 2024. The OIG conducted a site visit April 1–3, 2025, and conducted interviews virtually through August 6, 2025. The OIG identified a lack of quality assurance processes in place to prevent test errors and further evaluated laboratory leaders' oversight of operations and response to the identified concerns.

Background

The facility is a 160-bed, level 1b medical center that provides primary and specialty care, including cancer treatment and laboratory and pathology services.[1] The laboratory offers "a full range of clinical and diagnostic testing" and is divided into sub-specialty sections, such as hematology and blood bank.[2] From October 1, 2022, through September 30, 2023, the facility served 45,613 unique patients.

Pathology and Laboratory Medicine

Pathology is the study of what causes disease and subsequent effects on the body at a "cellular level."[3] Although the "main role" of a physician pathologist is "to use laboratory tests and techniques to determine the presence and type of disease in tissue and fluid samples," pathologists also collaborate with healthcare providers to help diagnose, treat, and monitor medical conditions.[4]

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[1] VHA Office of Productivity, Efficiency, & Staffing, "Fact Sheet Facility Complexity Model," August 14, 2024. The Facility Complexity Model "classifies VHA facilities at levels 1a, 1b, 1c, 2, or 3, with level 1a being the most complex and level 3 being the least complex." A level 1b facility is considered "high complexity" with "medium-high volume, high-risk patients, many complex clinical programs, and medium-large research and teaching programs."

[2] "John D. Dingell Department of Veteran Affairs Medical Center," VA, accessed May 8, 2025, https://www.va.gov/detroit-health-care/locations/john-d-dingell-department-of-veterans-affairs-medical-center/#health-care-offered-here; The sub-specialty of hematology, within pathology, focuses on "diseases that affect blood cells, blood clotting processes, bone marrow and lymph nodes." Laboratory blood bank staff "make sure blood transfusions are safe and direct the preparation and use of blood components." Cleveland Clinic, "Pathologist," accessed May 12, 2025, https://my.clevelandclinic.org/health/articles/24616-pathologist.

[3] Cleveland Clinic, "Pathologist."

[4] Cleveland Clinic, "Pathologist"; For the purposes of this report, the OIG uses the term "specimen" in lieu of "sample."

Clinical Laboratory Improvement Amendments (CLIA) set forth requirements regarding "procedures and oversight of U.S. laboratories that perform testing used in the diagnosis, treatment and prevention of diseases in patients."[5] To assure Veterans Health Administration (VHA) laboratory compliance with CLIA regulations, VHA uses quality and compliance agents in the National Enforcement Office (NEO), a division under VHA pathology and laboratory medicine (PLM). The NEO monitors laboratory performance and oversees facility laboratory proficiency testing, which is the periodic assignment of "unknown samples sent to a laboratory" for analysis and subsequent review.[6] As required by VHA Directive 1106, proficiency testing is conducted through a Centers for Medicare and Medicaid Services accredited provider, such as the College of American Pathologists (CAP), and requires laboratory staff to process specimens that the testing provider scores and evaluates.[7] VHA requires laboratory leaders and staff to participate in and report proficiency testing results "for every instrument and method (including backups) used for patient testing" to comply with federal regulations.[8]

Complete Blood Count and Complete Blood Count with Differential

Healthcare providers often order a complete blood count (CBC) to check a patient's general health or diagnose, monitor, and guide treatment for medical conditions.[9] A CBC measures the number of red blood cells, white blood cells, and platelets in the blood, and a CBC with differential details the number of different types of white and immature blood cells present, an indicator of immune system function.[10] For example, the presence of myeloblast cells (blasts),

[5] Basis and Scope, 42 C.F.R.§ 493.1 (2025); VHA Directive 1106, *Pathology and Laboratory Medicine Service,* January 24, 2024.

[6] VHA Directive 1106.

[7] "Laboratory Accreditation Program," College of American Pathologists (CAP), accessed February 12, 2025, https://www.cap.org/laboratory-improvement/accreditation/laboratory-accreditation-program; VHA Directive 1106. VHA requires all VA medical facility laboratories to participate in external Centers for Medicare and Medicaid Services-approved proficiency testing programs approved by the National PLM Quality and Compliance agent. The National PLM Quality and Compliance agent told the OIG that CAP is an approved proficiency testing provider, contracted with the NEO; CAP is an organization of board-certified pathologists that "serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide." "About the College of American Pathologists," CAP, accessed June 10, 2025, https://www.cap.org/about-the-cap.

[8] VHA Directive 1106.

[9] MedlinePlus, "Complete Blood Count (CBC)," accessed May 8, 2025, https://medlineplus.gov/lab-tests/complete-blood-count-cbc/.

[10] Cleveland Clinic, "Complete Blood Count (CBC)," accessed May 8, 2025, https://my.clevelandclinic.org/health/diagnostics/4053-complete-blood-count.

which are cells in the early stage of development inside bone marrow (not blood), could indicate cancer, such as acute myeloid leukemia (AML).[11]

Laboratory staff, such as a medical technologist, can use a hematology analyzer "to obtain complete blood count (CBC) results with or without differential[s]."[12] A hematology analyzer is a "laboratory instrument designed to automate the analysis of blood samples [specimens], providing detailed information about the various cellular components present in the blood."[13]

Facility Laboratory Supervisory Structure

The laboratory director, who is a pathologist, also serves as the chief of pathology and laboratory medicine and reports to the deputy chief of staff. The laboratory director oversees the pathologists, who are also medical directors of laboratory sub-specialty sections, including hematology and the blood bank.[14] Additionally, there is a laboratory manager who also reports to the laboratory director and oversees the medical technologists, including the section supervisors and the quality management technologist.

Allegations and Related Concerns

On November 29, 2024, the VA Office of Accountability and Whistleblower Protection notified the OIG of allegations regarding facility PLM services. The confidential complainant alleged that (1) "as recent as" late fall 2024, inaccurate identification and reporting of blasts, which can affect a provider's treatment plan, contributed to adverse outcomes for patients and (2) an off-tour medical technologist supervisor (the off-tour supervisor) "failed" a CAP proficiency test in July 2024.[15]

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[11] "About Acute Myeloid Leukemia (AML)," American Cancer Society, accessed April 14, 2025, https://www.cancer.org/cancer/types/acute-myeloid-leukemia/about.html; Myeloblasts are often referred to as "blasts" and for the purpose of this report, the term blasts will be used. Cleveland Clinic, "Blast Cells," accessed May 9, 2025, https://my.clevelandclinic.org/health/body/blast-cells; "Tests for Acute Myeloid Leukemia (AML)," American Cancer Society, accessed April 9, 2025, https://www.cancer.org/cancer/types/acute-myeloid-leukemia/detection-diagnosis-staging/how-diagnosed.html; Acute myeloid leukemia is a type of fast-growing blood cancer that originates in the bone marrow and moves into the blood. "About Acute Myeloid Leukemia (AML)" American Cancer Society.

[12] Gene Gulati, Guldeep Uppal, and Jerald Gong, "Unreliable Automated Complete Blood Count Results: Causes, Recognition, and Resolution," *Annals of Laboratory Medicine*, 42, no. 5 (September 1, 2022): 515-530, https://doi.org/10.3343/alm.2022.42.5.515.

[13] "Hematology Analyzers: Purpose, Function, & Uses," Free CME, accessed May 6, 2025, https://www.freecme.com/clinical-resources/hematology/hematology-analyzer; Hematology is "the study of blood and blood disorders." These disorders include, among others, anemia, infection, and leukemia. "Hematology," John Hopkins Medicine, accessed May 6, 2025, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/hematology.

[14] During an interview, the laboratory director told the OIG about the section medical director roles.

[15] The laboratory manager told the OIG that the supervisor provided oversight of the off-tour medical technologists, which refers to technologists working on the afternoon or midnight shifts. Additionally, the confidential complainant also provided allegations related to personnel and employee relations that are outside the scope of this inspection and will not be addressed in this report.

The complainant later clarified that the inaccurate reporting of blasts in fall 2024 was associated with one patient and was the result of multiple medical technologists not identifying the presence of blasts.[16]

In late January 2025, after reviewing the allegations and the patient's electronic health record (EHR), the OIG noted numerous erroneous blood results may indicate lapses in laboratory quality assurance processes. Due to these concerns, the OIG included review of laboratory quality assurance processes and laboratory leaders' response in this inspection.

Scope and Methodology

The OIG opened the inspection on March 6, 2025, and conducted a site visit April 1–3, 2025. The OIG conducted additional interviews virtually through August 6, 2025. The OIG interviewed the complainant; National PLM Quality and Compliance agent; Veterans Integrated Service Network (VISN) 10 PLM point of contact for laboratory services as well as relevant facility leaders, and PLM staff.

The OIG reviewed relevant federal, VHA, and facility policies and procedures; laboratory regulatory and accrediting audits, reviews, and applicable action plans; Joint Patient Safety Report (JPSR) data; organizational charts; and committee meeting minutes.[17] Additionally, the OIG examined facility laboratory data records from May through October 2024 and relevant EHRs.[18] The OIG did not independently verify VHA data for accuracy or completeness.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, as amended, 5 U.S.C. §§ 401–424. The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a

[16] The OIG interviewed the complainant in February 2025, before announcing the inspection, to obtain clarification on the allegations. The complainant denied knowledge of adverse outcomes and expressed unawareness to why the supervisor did not pass the CAP proficiency testing.

[17] The JPSR is "a mandated web-based system used by VHA employees to report patient safety events." VHA Directive 1050.01(1), *VHA Quality and Patient Safety Programs*, March 24, 2023, amended March 5, 2024.

[18] The OIG learned from the laboratory information manager that data records indicate the following for each specimen: what test the medical technologist performed and when; the test results and when they were released to the EHR; and if test results were corrected, when, by whom, and the corrected values.

specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

The OIG conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Patient Case Summary

The patient, who was in their seventies, had a history of congestive heart failure with a diagnosis of AML approximately two years earlier, for which the patient received chemotherapy treatment for about one year.[19] An oncologist provided follow-up care and documented that the patient was in remission indicated by results of a bone marrow biopsy performed in early 2024.

Four months later, the patient was seen in the facility emergency department for shortness of breath, and the emergency department provider diagnosed the patient with pneumonia and heart failure. The patient's laboratory study of a CBC with differential revealed low blood counts and blast cells of 67 percent, and a physician arranged for immediate transfer to a higher level of care. Two days after transfer, the patient had a bone marrow biopsy that confirmed relapse of AML and the oncologist restarted chemotherapy.

In early fall 2024, while continuing chemotherapy treatment, the patient had another bone marrow biopsy. Eighteen days later, prior to the bone marrow biopsy results being finalized, the patient presented to the facility emergency department for shortness of breath. The emergency department physician documented the patient's laboratory study of a CBC with differential showed 4 percent blasts, as well as "… the patient already has AML and is on chemo[therapy] for this was not felt to represent acute change." The emergency department provider diagnosed the patient with pneumonia and started antibiotics, and a hospital physician admitted the patient for further treatment (hospital day 1).

Laboratory results entered into the EHR on hospital days 2 and 3 indicated no blasts. On hospital day 4, the oncologist documented a discussion with a pathologist that the results of the bone marrow biopsy performed 21 days prior were still pending.[20] The oncologist also documented the pathologist communicated a peripheral smear read performed that day showed "a large number of blasts concerning for relapsed AML" and further testing was indicated.[21] The oncologist ordered a phenotyping evaluation by flow cytometry.[22] On hospital day 6, the additional testing results showed 87 percent blasts and confirmatory testing returned with 90 percent blasts consistent with AML relapse. With these laboratory results, the oncologist discussed new chemotherapy options with the patient, but the patient was not a candidate for chemotherapy

[19] The OIG uses the singular form of they, "their" in this instance, for privacy purposes.

[20] Review of the EHR showed the bone marrow results were finalized on the day after the patient's hospital discharge and showed no evidence of recurrent acute leukemia based on the sample from early fall 2024.

[21] A peripheral smear (also known as a blood smear) is a laboratory technique where a thin layer of blood is stained on a glass slide to examine red blood cells, white blood cells (WBCs)s, and platelets under a microscope. A laboratory technician, such as a medical technologist, uses a peripheral smear to perform a differential. MedlinePlus, "Blood Smear," accessed April 28, 2025, https://medlineplus.gov/lab-tests/blood-smear/; Hospital day 4 was a Monday, and the pathologist's peripheral smear reading was from the specimen collected on hospital day 2.

[22] Phenotyping evaluation by flow cytometry is a specialized laser-based blood test that analyzes the chemical and physical properties of each blood cell to determine the type. At the facility, this test is completed by the pathologist and confirmed by an outside non-VA laboratory when requested.

until pneumonia treatment was completed with a return to baseline health. On hospital day 8, the tumor board documented the patient's chemotherapy remained on hold.[23]

The patient completed treatment for pneumonia and requested to be discharged home on hospital day 14. Seven days later, EHR documentation reflected that the hematology supervisor corrected 11 of the patient's blood count differential results. The 11 corrections spanned from hospital day 1 through hospital day 14 (see table 1).

Twelve days after the discharge, a physician readmitted the patient to the hospital for worsening cough with increased difficulty breathing, and the patient died several days later.

Table 1. Original and Corrected Blast Cell Readings

Hospital Day	Medical Technologist	Original Manual Blast Cell % Reported	Corrected Manual Blast Cell % Reported
1	Medical Technologist 1	4	51
2	Medical Technologist 2	0	65
3	Medical Technologist 3	0	73
4	Medical Technologist 4	0	79
5	Medical Technologist 5	0	85
6	Medical Technologist 4	0	84
7	Medical Technologist 6	0	92
10	Medical Technologist 7	0	94
11	Medical Technologist 8	0	89
13	Medical Technologist 4	0	75
14	Medical Technologist 3	0	85

Source: OIG synthesis of CBC differential counts from EHR and laboratory documents.
Note: A blast cell percentage of zero indicates the technologist did not identify any blasts in the specimens.[24] Additionally, CBC with differential results are not represented on hospital day 8 as no inaccurate result was found, and on days 9 and 12, the patient's EHR indicated a CBC with differential had been completed in the previous 24 hours.

[23] VHA Directive 1415, *VHA Oncology Program*, April 9, 2020. "A tumor board is a multidisciplinary case conference that convenes at individual VA medical facilities and nationally to discuss the diagnosis, staging, and management of patients with cancer."

[24] A manual CBC differential counts each different type of WBC contained within a 100-cell specimen. This count of each different type of WBC may be reported as a percentage of all the WBCs in the 100-cell specimen. Example: 30 cells in the 100-cell specimen are identified as blasts, therefore, the blast cell result would be 30 percent. Cleveland Clinic, "Complete Blood Count (CBC)"; Kathy Doig and Leslie A. Thompson, "Focus: Interpreting the Complete Blood Count, A Methodical Approach to Interpreting the White Blood Cell Parameters of the Complete Blood Count," *American Society of Chemistry and Laboratory Science* 30 no. 3 (Summer 2017), https://clsjournal.ascls.org/content/ascls/30/3/186.full.pdf.

Inspection Results

1. Inaccurate CBC with Differential Results and Deficiencies in Quality Assurance

The OIG substantiated multiple medical technologists reported inaccurate CBC with differential results for the patient; however, the OIG did not identify adverse clinical outcomes related to these inaccuracies.[25] Further, the OIG found laboratory leaders lacked a quality assurance process to ensure the accuracy of CBC with differential results.[26]

Inaccurate CBC with Differential Results

The OIG reviewed the patient's EHR for manual CBC with differential laboratory studies performed in fall 2024 and found 11 of 13 studies, completed by eight medical technologists, contained inaccurate blast results.[27] The OIG found the medical technologists either missed the presence of, or under reported the percentage of, blasts in the blood specimens.[28]

After a provider orders a CBC with differential, the patient's blood specimen is delivered to the laboratory, and a medical technologist performs an analysis of the specimen.[29] (See figure 1.)

[25] Multiple cellular components of the CBC with differential were inaccurately reported, however, blasts are the focus of this inspection.

[26] Laboratory leaders include the hematology medical director and supervisor, as well as the laboratory manager.

[27] A CBC with differential result produced by the hematology analyzer is referred to as an automated differential. A CBC with differential result produced by a medical technologist reviewing the blood specimen under a microscope is referred to as a manual differential.

[28] The term "missed" indicates that blasts were present in the CBC with differential blood specimen but were not recognized by the medical technologist. The term "under reported" means the medical technologist identified blasts in the blood specimen but reported a percentage lower than what was present.

[29] Facility Policy HEM 017 (2.0), *Resulting Sysmex XN-9100 Print-Offs For CBC With Differential*, October 2, 2024. This policy was replaced by Facility Policy HEM 017 (3.0), *Resulting Sysmex XN-9100 Print-Offs for CBC with Differential*, April 2, 2025, and subsequently Facility Policy HEM 017 (4.0), *Resulting Sysmex XN-9100 Print-Offs for CBC with Differential*, April 11, 2025. The HEM 017 (2.0) version of this policy was in effect at the time of the event and the policies contain similar language related to analysis of a specimen.

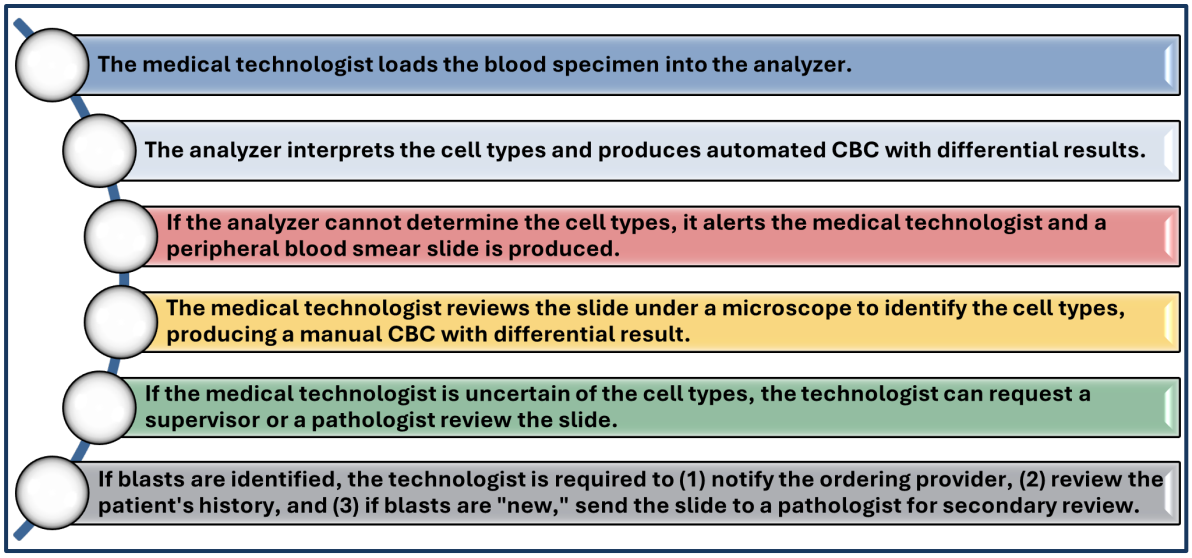

Figure 1. *CBC With Differential Determination Process:*
Source: Facility policy HEM 017 (2.0), Resulting Sysmex XN-9100 Print-Offs for CBC with Differential,
October 2, 2024; Sysmex, Automated Haematology Analysers, XN-9000 Series, accessed June 18, 2025, https://www.sysmex-ap.com/wp-content/uploads/2020/08/Sysmex_XN9000-series_2019-ebook.pdf and information from OIG interviews.
Note: The hematology supervisor told the OIG that if a medical technologist is uncertain about the cell types, the technologist can ask a supervisor or a pathologist to review slides. The laboratory director told the OIG that "new" blasts refer to blasts that are seen for the first time or reappear after a patient has received treatment.

The OIG reviewed the patient's EHR and laboratory data for the 11 inaccurate results and found that medical technologist 1 under reported blasts and medical technologists 2 through 8 missed blasts. Further, medical technologists 3 and 4 missed blasts on multiple specimens during the patient's hospital course.

The OIG found a pervasiveness of inaccurate CBC with differential results over the patient's hospital course. A review of the patient's EHR indicated that on hospital day 1, medical technologist 1 manually examined the blood smear slide, found blasts, and notified the emergency department provider. During an interview, medical technologist 1 recalled identifying the presence of blasts and subsequently reviewing the patient's EHR for prior blasts, finding no such history.[30] Medical technologist 1 told the OIG of under reporting blasts due to infrequently encountering the cells, further sharing the belief that the number of blasts was higher but stated,

[30] The patient received oncology care at the Ann Arbor VA Medical Center before being admitted to the facility in fall 2024. The OIG reviewed the EHR and found no positive blast test results from the Ann Arbor VA between summer and fall 2024. Medical technologist 1 did not indicate how far back the EHR was reviewed. The laboratory director told the OIG the look back period is "typically determined on a case by case basis and according to [the medical technologist's] discretion."

"I do get scared to call blasts even when I do see them" and "they're not supposed to be in the blood."[31]

Also, medical technologist 1 told the OIG a peripheral blood smear slide was sent to a pathologist for secondary review. However, the OIG did not find evidence that a slide was submitted.[32] The laboratory director explained to the OIG that a "new" blast, which requires a secondary review by a pathologist, is one seen for the first time or a blast that reappears after treatment.

The following day (hospital day 2), medical technologist 2 manually reviewed that day's blood specimen and missed the presence of blasts; however, the technologist submitted the specimen for a pathologist's secondary review. The hematology medical director told the OIG that on hospital day 4, the specimen (from hospital day 2) was found to have greater than 50 percent blasts present and this result was reported by phone to the patient's oncologist.[33] The oncologist documented receiving the verbal notification from the hematology medical director. The OIG found no evidence that the laboratory data was corrected to show the presence of blasts in the EHR at that time.

During interviews, the OIG learned that the hematology supervisor and laboratory manager became aware of the inaccurate results after a JPSR was submitted in fall 2024. The OIG found the hematology supervisor made corrections in the EHR for all 11 results. The hematology supervisor also completed a variance report and informed the oncologist of the corrections as required.[34] Further, the oncologist told the OIG of being informed about the presence of blasts on hospital day 4. The oncologist explained neither the delayed knowledge of the CBC with differential result, nor the specimens corrected after the patient's hospitalization, affected the patient's care or outcome.

The OIG asked laboratory leaders about the magnitude of inaccurate results as multiple technologists missed or under reported the percentage of blasts:

- The hematology medical director and hematology supervisor explained that the facility serves a low volume of patients with AML and other conditions where blasts may be present, and medical technologists tend to under report or misidentify blasts.

[31] Cleveland Clinic, "Blast Cells." "Having 20 [percent] or more blasts in your bone marrow or blood is a sign of various forms of leukemia."

[32] At the time of the incident, there was no established policy or requirement to document when slides were sent for pathology review in the EHR. The hematology supervisor and the hematology medical director told the OIG that the slide from hospital day 1 was not submitted for a pathologist review.

[33] Medical technologist 2 completed the hospital day 2 CBC with differential analysis over a weekend and the blood specimen was reviewed by the pathologist on hospital day 4.

[34] Facility Policy GEN007, *Safety and Quality Concern Reporting Policy*, June 19, 2007, revised April 1, 2021. A variance report allows laboratory staff to report quality and patient safety concerns, such as a wrong result, data entry error, or a delay in treatment, to laboratory management for process improvement.

- The hematology supervisor stated that CAP selects and sends peripheral blood slides to be used for cell identification as a part of the annual competency for medical technologists, but slides do not always contain blast specimens.
- The laboratory manager reported that this specific patient case highlighted the problems related to the medical technologists missing or under reporting blasts.

A "commitment to resilience" is one of VHA's high reliability organization principles.[35] "Commitment to resilience" means getting back on track after mistakes and preventing repetition of mistakes in the future.[36] Additionally, high reliability "focuses on strengthening practices that reduce error," and "continuously learning" from errors.[37] Considering multiple medical technologists contributed to inaccurate results for CBC with differential tests, and VHA's commitment to resilience, the OIG inquired about feedback to the medical technologists regarding the errors.[38]

The OIG learned the hematology supervisor typically addresses staff individually, to learn why an error occurred and provide instruction on what should occur. However, for the inaccurate CBC with differential results in fall 2024, the hematology supervisor reported addressing technologists generally during a huddle for the off-shift staff, as not to "single everyone out."[39] The OIG requested and reviewed the referenced huddle note and confirmed that the hematology supervisor met with staff in fall 2024. However, the OIG found the huddle note lacked detail regarding the identified errors, did not include a discussion of the corrected EHR entries, and reflected that only four medical technologists were present. The OIG also noted that only one of the four medical technologists present at the fall 2024 huddle contributed to the patient's inaccurate CBC with differential results.

Further, the OIG interviewed the eight medical technologists identified as reporting inaccurate blasts and learned the technologists were not aware of the corrected CBC with differential results until the OIG notice of inspection and in preparation for OIG interviews. One technologist stated, "I would like to know that [a result] was changed or if I missed something … I didn't know."

The OIG questions the effectiveness of using staff huddles as the primary method of communication for important practice changes to prevent repeat errors that risk patient safety. In this case, none of the medical technologists involved in the inaccurate readings recalled awareness of the errors prior to the OIG inspection. The OIG would expect laboratory

[35] VHA, *VHA High Reliability Organization (HRO) Reference Guide*, September 2024.

[36] VHA, *VHA High Reliability Organization (HRO) Reference Guide*.

[37] VHA, *VHA High Reliability Organization (HRO) Reference Guide*.

[38] VHA, *VHA High Reliability Organization (HRO) Reference Guide*.

[39] The hematology supervisor reported addressing the errors with the off-shift staff as most of the errors occurred during that shift.

supervisors to ensure medical technologists receive feedback regarding errors made to promote continuous learning and prevent risks to patient safety.

Deficiencies in Laboratory Quality Assurance Processes

The OIG found deficiencies in the quality assurance process to monitor the accuracy of medical technologists' identification of blasts. Specifically, laboratory leaders had not implemented ongoing reviews of medical technologists' accuracy in cell identification, despite knowledge of the technologists' errors in reading the patient's specimens in fall 2024.[40]

VHA policy states the laboratory director is responsible for ensuring a "sufficient number of appropriately educated, experienced and trained testing personnel are employed by the VA medical facility laboratory to provide appropriate consultation, properly supervise and accurately perform tests and report test results."[41] Additionally, "there must be procedures to verify patient results are accurately transmitted from the point of data entry (interfaced instruments and manual input) to patient reports."[42]

During an interview, the hematology supervisor explained that quality assurance reviews are conducted for 10 percent of manual CBC differential results. However, the supervisor further explained this review focuses on the accuracy of the medical technologists' entry of test results into the EHR, as required, and does not assess the accuracy of technologists' cell identification. Further, the laboratory manager and the hematology medical director informed the OIG that no quality assurance metrics were in place to detect the medical technologists inaccurately identified blasts during the patient's hospitalization in fall 2024. They expressed this situation highlighted the necessity of establishing such metrics. The hematology medical director stated, "We're going to implement [a process] … because of this patient."

The National PLM Quality and Compliance agent told the OIG that NEO does not track hematology quality assurance metrics, and the laboratory director has the discretion to implement quality assurance metrics specific to the facility laboratory. Additionally, the National PLM Quality and Compliance agent stated VISN staff are not typically involved in the monitoring of laboratory metrics and communications between NEO and facility laboratory directors. The National PLM Quality and Compliance agent further explained that by design, the VISN is only involved if notified of upcoming laboratory audits, audit findings, or any disruption or cessation of laboratory services resulting from findings or proficiency testing failures.

The OIG determined that eight medical technologists missed or under reported blasts in 11 of the patient's 13 CBC with differential laboratory studies; however, no adverse clinical outcomes

[40] Laboratory leaders include the laboratory director and manager, as well as the hematology medical director and supervisor.

[41] VHA Directive 1106.

[42] VHA Directive 1106.

were identified. The OIG concluded that the lack of a quality assurance process to monitor the accuracy of blast identification remains a risk to patient safety. Additionally, the leaders did not notify medical technologists of inaccurate blast results, which precluded mitigation of errors and limited proficiency improvement.

2. Laboratory Leaders' Response to Inaccurate Reporting

The OIG determined that once aware of the inaccurate CBC with differential results, the laboratory manager developed an action plan to change policy and improve staff competencies. However, the OIG found that laboratory leaders did not (1) implement the planned corrective action until spring 2025, or (2) complete the actions until about six months after development.[43] Further, at the time of the site visit in early April 2025, the OIG requested the chief of staff ensure a review of CBC with differential results be completed to evaluate accuracy and assess competency.

Fall 2024—Planned Action

VHA tasks laboratory directors with responsibility for "directing and coordinating" patient care functions of the laboratory.[44] Further, laboratory directors are responsible for ensuring laboratory personnel operations and services "are run efficiently and effectively."[45]

During interviews, the laboratory manager told the OIG that in fall 2024, patient safety staff requested a response to a report of inaccurate results. The laboratory manager reported meeting with the hematology medical director and hematology supervisor the day after the notification to gather information and develop an action plan.[46] The laboratory manager believed inaccurate CBC with differential results were due to medical technologists' lack of policy knowledge or proficiency. Therefore, the action plan addressed both causes—a change to laboratory policy regarding CBC with differential testing and additional competencies for all technologists working in hematology.[47]

Policy Change

The OIG found the hematology supervisor and laboratory director changed the CBC with differential policy to require pathologists complete a secondary review of specimens with abnormal cells (such as suspicious for blasts); however, the policy change took almost five

[43] Laboratory leaders include the laboratory director and manager and the hematology medical director and supervisor.

[44] VHA Directive 1106.

[45] VHA Directive 1106.

[46] The OIG learned that the former laboratory director was on leave and not present at this meeting. According to the chief of quality and patient safety, a new laboratory director started in fall 2024.

[47] Competency refers to staff's ability to demonstrate necessary skills and abilities to perform work tasks. Facility Policy GEN031, *Competency Assessment (3.1)*, December 30, 2014, effective August 2, 2024.

months to initiate and two weeks to complete.[48] In fall 2024, at the time of the inaccurate CBC with differential results, medical technologists were not required to send peripheral blood smear slides for secondary pathologist review unless the technologist detected "new" blasts.[49]

In March 2025, the OIG notified the facility about this inspection. Following the notification, the hematology supervisor revised the facility policy to require medical technologists to send peripheral blood smear slides with "suspicious cells" to a pathologist for secondary review.[50] In a written communication to the OIG, the hematology medical director clarified that for "suspicious cells," the medical technologists have been instructed to send slides with blasts or "possible blasts" to a pathologist for secondary review.

Less than one month later, in April 2025, and about five months from the planned policy revisions in
fall 2024, the laboratory director approved the revised policy.[51] The OIG questioned the laboratory director about the delay in initiating the policy revision and the director stated, "I don't know why it took so long."

Competency Plan

The OIG found the hematology supervisor created the medical technologists' additional competencies as planned; however, laboratory leaders did not ensure the additional competencies were timely initiated and completed.[52] Also, although aware of the inaccurate CBC with differential results and the associated action plan, neither the patient safety managers nor the laboratory quality management technologist followed up to ensure completion of the planned actions as required.[53]

Medical technologists must complete competencies upon hire, again in six months (after the initial new employee competency), and annually thereafter.[54] The laboratory director and hematology supervisor told the OIG the additional competency implemented by laboratory

[48] Facility Policy HEM 017 (2.0); Facility Policy HEM 017 (3.0).

[49] Facility Policy HEM 017 (2.0).

[50] Facility Policy HEM 017 (2.0); Facility Policy HEM 017 (3.0). Laboratory leaders revised version 3.0 of the policy to require pathologist review if a medical technologist observed suspicious cells on a peripheral blood smear slide. The laboratory manager also reported a second policy change to eliminate the ability for medical technologists to defer completion of a manual CBC with differential when one was completed within the last 24 hours.

[51] Facility Policy HEM 017 (2.0); Facility Policy HEM 017 (3.0). Laboratory leaders revised version 3.0 of the policy to require pathologist review if medical technologists observe suspicious cells on a peripheral blood smear slide.

[52] Laboratory leaders include the laboratory director and manager, as well as the hematology medical director.

[53] Patient safety managers should ensure that "immediate actions are taken following a patient safety event." VHA Directive 1050.01(1); Facility Policy GEN007. In an additional role, the laboratory quality management technologist has responsibility to ensure the Quality Assurance Committee assesses the effectiveness of actions taken in response to reports regarding patient safety.

[54] Facility Policy GEN031, *Competency Assessment (3.1)*, December 30, 2014, effective August 2, 2024.

leaders, as a part of the planned corrective action, was focused on manual differential analysis and cell identification.

During interviews, the laboratory manager explained the decision, made with the hematology medical director and supervisor, to conduct additional competencies for all medical technologists who work in hematology was necessary to ensure safe patient care. The hematology supervisor said the purpose of the additional competency was to assess the technologists' ability to (1) identify the presence of blasts and (2) accurately determine the percentage of blasts present. The hematology supervisor described the additional competency as two-tiered, which the medical technologists either passed or failed.

- If the technologist correctly identified blasts, the technologist would pass.
- If the technologist did not identify the presence of blasts when blasts were present, the technologist failed and required retraining.

The hematology supervisor reported that medical technologists were also required to correctly determine a percentage of blasts present on the applicable slides and if the technologist did not, refresher training was required to "be able to identify blast cells more confidently."[55]

In January and March 2025, after the OIG inspection announcement, the hematology supervisor implemented the competency plan to each of the 23 medical technologists who worked in hematology.[56] According to the hematology supervisor, medical technologists were given 10 slides that required manual reading for CBC with differential specimens.

By mid-spring, almost six months after laboratory leaders first became aware of the inaccurate CBC with differential results, all 23 medical technologists completed the additional competency. The hematology supervisor reported that of the 23 medical technologists, 3 failed as they did not identify the presence of blasts, and 4 did not accurately determine the percentage of blasts present, thus requiring retraining. Only one of these 7 medical technologists was also one of the 8 technologists responsible for the patient's inaccurate CBC with differential results in fall 2024. Therefore, the OIG found the additional competency identified 6 more medical technologists who determined inaccurate results when performing a CBC with differential.

During an interview, the hematology supervisor reported taking remedial steps such as temporary removal of medical technologists who either failed the competency or required retraining. In May 2025, the hematology supervisor reported that 2 of the 7 medical technologists

[55] The hematology supervisor also told the OIG that refresher training, which consisted of showing technologists examples of abnormal cells, served as a "confidence boost" to identify blasts.

[56] Two of the 23 medical technologists assessed in January 2025 did so as a part of a regularly scheduled competency review.

were working in hematology.[57] To ensure accuracy of the technologists' CBC with differential results, all the technologists' peripheral blood smear slides were reviewed by the hematology supervisor or lead technologist—no "discrepancies" or concerns in the technologists' reads were found. The hematology supervisor told the OIG about the goal to return the remaining 5 technologists to hematology by July 2025, after the technologists receive applicable training and the supervisor reviews the technologists' peripheral blood smear slides for accuracy.[58]

Although additional competencies for all medical technologists working in the hematology section were completed, the OIG is concerned that timely initiation did not occur. When the OIG asked about the delays,

- the laboratory manager explained that the hematology supervisor, who was responsible for completing the additional competencies, had to send the specimen slides to one medical technologist at a time, so answers could not be shared; and
- the hematology supervisor explained that technologists were completing the competency in addition to their regular workload.

However, when the OIG asked why it took several months from devising the plan to conduct additional competencies in fall 2024 to initiating the additional competencies in spring 2025, the hematology supervisor told the OIG, "I'm not sure." Considering inaccurate CBC with differential results occurred across multiple medical technologists, and VHA's commitment to resilience, the OIG is concerned with laboratory leaders' delayed initiation of additional competencies, thereby patient safety risks were not mitigated.[59]

During an interview, the laboratory director denied having knowledge of the patient's inaccurate CBC with differential results in fall 2024 or the associated plans for policy change and additional competencies until receiving notification of the OIG inspection in March 2025.[60] The laboratory director reported that once becoming aware of the plan for additional competencies, "pushing" for completion and further stated, "if I don't push for it, it's [going] to even take longer." The laboratory director believed there was a lack of communication from patient safety staff about the laboratory-devised action plan.

[57] Laboratory leaders explained that medical technologists may rotate assignments to work in all sections of the laboratory or rotate less frequently and specialize in particular areas of the laboratory such as hematology or blood bank.

[58] The hematology supervisor confirmed that by early August 2025, all seven medical technologists had received required training and returned to work in the hematology section.

[59] VHA, *VHA High Reliability Organization (HRO) Reference Guide*.

[60] The laboratory director also told the OIG that being new to the role, in fall 2024, may have been a factor in unawareness to the inaccurate CBC with differential results and the associated response.

Facility Patient Safety Managers Response to Inaccurate CBC With Differential Results

VHA tasks patient safety managers with "[v]alidating that immediate actions are taken following a patient safety event that protect other patients from harm."[61] Therefore, the OIG interviewed two patient safety managers who were aware of and reviewed the laboratory leaders' response to the fall 2024 report of inaccurate CBC with differential results. The OIG learned patient safety managers do not track completion of service level action plans implemented in response to patient safety reports. One patient safety manager stated, "That's [the laboratory] manager's responsibility." However, the chief of quality and patient safety told the OIG that patient safety staff "have some responsibility and ownership into ensuring that action plans [are not] just written out but that they're actually being worked on." Further, the chief of quality and patient safety said the laboratory quality management technologist's role could be "maximized," recognizing an opportunity to work more collaboratively with and offer support to the laboratory quality management technologist to reduce delays in completion of corrective actions.[62]

In review of the position description for the laboratory quality management technologist, the OIG found the requirement to provide "authoritative consultative services to management at all levels of the organization as it applies to quality management in a clinical laboratory setting." However, the OIG found a discrepancy in understanding of the laboratory quality management technologist's role:

- The laboratory manager, who supervises the quality management technologist, explained that the technologist "may not be performing all the duties … on a day-to-day basis as some of the tasks might be shared across multiple positions in the laboratory."
- The laboratory quality management technologist denied overlap of responsibilities and believed staff within each laboratory section are the "quality assurance experts."

Additionally, when referring to the corrective action following the inaccurate CBC with differential results, the laboratory quality management technologist told the OIG, "Unfortunately, I didn't have much involvement. … it doesn't really overlap with me … I'm not [the] hematology supervisor."

The OIG concluded that laboratory leaders planned a response that addressed inaccuracies in medical technologists' reading of blasts; however, the initiation to implement action was not timely and occurred after the OIG inspection announcement. The OIG determined the laboratory director did not ensure timely completion of corrective action as policy change and medical technologist additional competencies took about six months to complete. Further, despite awareness, patient safety managers did not ensure action items were completed to reduce risk of future reoccurrence, and the OIG is concerned that the unclear role and responsibilities of the

[61] VHA Directive 1050.01(1).

[62] According to the laboratory organizational chart, the quality management technologist reports directly to the laboratory manager, not the laboratory director.

laboratory quality management technologist affected the ability to resolve quality concerns regarding patient care.

Retrospective Facility Reviews

The OIG found that despite awareness of CBC with differential inaccuracies by multiple technologists in the fall of 2024, the laboratory director and manager did not ensure comprehensive retrospective reviews to monitor accuracy until after the OIG site visit in spring 2025.

VHA defines high reliability as "exceptional care [that] is consistently delivered for every patient, every time" and VHA's journey to become a high reliability organization is founded on a continuing commitment to harm prevention and process improvement.[63] Additionally, every VA medical center laboratory director must have a PLM quality management program that, in part, "[e]nsur[es] the availability of test results and reports that are accurate, reliable and of high quality."[64]

During interviews with the laboratory manager and director, the OIG asked if retrospective reviews of other patients were conducted to identify if adverse outcomes or risks to patient safety occurred as a result of inaccurate CBC with differential readings. The laboratory manager reported peripheral blood smear slides were not reviewed; however, the manager reported checking "critical" laboratory results for a "couple months back" from fall 2024 for any patients where blasts were identified, and reported no awareness of any additional patients with inaccurate results.[65] The OIG is concerned that the manager did not review specimen slides, including those with "normal" results, to determine whether the medical technologists' readings were accurate and therefore, could not be sure if blasts were missed for other patients. When referring to completion of retrospective reviews, the laboratory director stated, "We will" and explained reviews should continue "for a while."

On April 3, 2025, while on-site and after learning laboratory leaders conducted no comprehensive retrospective reviews, the OIG requested facility leaders ensure CBC with differential results, including blasts, were accurately reported. Further, the OIG requested that laboratory leaders track, monitor, and identify trends resulting from pathologist secondary reviews of CBC with differentials.

In May 2025, the laboratory director told the OIG that for the months of February, March, and April, three pathologists reviewed 10 percent of the peripheral blood smear slides to verify the

[63] VHA, *VHA High Reliability Organization (HRO) Reference Guide*.

[64] VHA Directive 1106.

[65] Since critical laboratory results were the trigger for review, the laboratory manager denied reviewing normal results and stated, "maybe we should change that." The laboratory manager also told the OIG that following the inaccurate CBC with differentials in fall 2024, all peripheral blood smear slides for the patient were reviewed and some of the results were deemed normal by the medical technologists.

accuracy of medical technologists' CBC with differential reads.[66] Specifically, pathologists reviewed approximately 90 slides that the hematology analyzer flagged for blasts, atypical lymphocytes, or immature cells. Additionally, the hematology medical director reviewed all peripheral blood smear slides identified by the hematology analyzer to be suspicious for presence of blasts or abnormal lymphocytes in the first half of April 2025. After two weeks of review, the hematology medical director "found no discrepant differentials or missed blasts" pertaining to the medical technologists' readings.[67]

The OIG reviewed the retrospective review document the hematology supervisor provided and noted that pathologists disagreed with two medical technologists' blast related reads for two patients. The OIG reviewed the two patients' EHRs and found no impact on the patients' care.[68]

To address continued monitoring and tracking the accuracy of CBC with differential results, the laboratory director told the OIG that the retrospective reviews will continue monthly, as a quality assurance monitor, and will be reported to the laboratory Quality Assurance Committee.[69] The laboratory quality management technologist confirmed that committee monitoring of the accuracy in CBC with differential results will begin in June 2025. [70]

The OIG concluded that pathologists, including the laboratory director and hematology medical director, completed the OIG-requested retrospective review and plan for continued quality assurance monitoring; however, the OIG remains concerned that medical technologists may continue to misread blasts without sustained oversight.

3. Laboratory Leaders' Did Not Ensure Corrective Action

The OIG reviewed laboratory policy and procedures and found deficiencies in the laboratory quality assurance process. Specifically, laboratory leaders did not fully investigate the CBC with

[66] The OIG found the laboratory director and hematology medical director were two of the three pathologists who conducted the retrospective review. The OIG also learned from the hematology supervisor peripheral blood smear slides are kept up to 60 days, longer than the required 7 days, which allowed pathologists to complete a retrospective review as far back as February 2025. VA Diagnostic Services, "Record and Specimen Retention Guidelines for Pathology and Laboratory Medicine," January 21, 2025 (6.1).

[67] Additionally, the hematology medical director told the OIG that ongoing pathologist review of peripheral blood smear slides will continue as outlined in policy. Facility Policy HEM 017 (4.0).

[68] The OIG reviewed the patients' EHRs for the CBC with differential results, as well as communication of and corrections regarding the results, and subsequent treatment provided in response to the presence of blasts.

[69] Facility Policy GEN007. The Quality Assurance Committee reviews monthly laboratory data on reported quality concerns, determines applicable corrective action, and provides follow up to assess effectiveness of actions taken.

[70] In early September 2025, the laboratory quality management technologist confirmed the committee began monitoring the accuracy of CBC with differentials in mid-June 2025.

differential inaccuracies or track the effectiveness of actions in response to the variance report as required.[71]

Laboratory staff must report all quality and patient safety concerns by using a variance report form, which is used to review, trend, and identify opportunities for improvement. Once a concern is identified, laboratory staff must submit a variance report to the section supervisor for immediate investigation "to ensure that the problem/issue has been addressed appropriately."[72] "[Supervisors] should make every attempt to review and investigate the variance report within 24 hours and sign and date the variance report once the investigation is complete."[73] After confirming the concern has been addressed, the section supervisor provides the variance report form to the laboratory quality management technologist for review, who then provides the document to the laboratory manager and director to review and approve. [74]

Facility policy also requires the laboratory Quality Assurance Committee to review variance reports and "determine if corrective action is needed and how it will be taken."[75] If a variance requires more "intensive investigation," "[a] full investigation and corrective action should be submitted by the next Committee meeting" and "[t]he committee will also provide follow-up to assess the effectiveness of the action taken."[76]

The OIG reviewed documentation and confirmed that a variance report regarding the inaccurate CBC with differential results was completed and signed by the hematology supervisor approximately one month later. The laboratory quality management technologist signed the variance report the next day. However, the variance report was (1) not signed by the laboratory manager or director as required and (2) did not have a space for either signature.[77]

The OIG also reviewed Quality Assurance Committee meeting minutes from fall 2024 through spring 2025 and confirmed the variance report was included for committee review in fall 2024; however, the minutes lacked detail and did not reflect discussions about follow-up or monitoring of corrective actions. The OIG also noted committee member attendance included laboratory

[71]Laboratory leaders include the laboratory director and manager, hematology medical director and supervisor, as well as the quality management technologist. Facility Policy GEN007. A variance report allows laboratory staff to report quality and patient safety concerns, such as a wrong result, data entry error, or a delay in treatment, to laboratory management for process improvement.

[72] Facility Policy GEN007.

[73] Facility Policy GEN007.

[74] Facility Policy GEN007. Policy states the "QA [Quality Assurance] coordinator … reviews the [variance] report"; however, the laboratory quality management technologist told the OIG of carrying out the roles of Quality Assurance coordinator, as described in the policy.

[75] Facility Policy GEN007.

[76] Facility Policy GEN007.

[77] Facility Policy GEN007. Laboratory policy requires the signature of either the laboratory manager or director on the variance report "[t]o ensure that each variance is addressed appropriately and that management is aware of problem situations."

leaders and supervisors, as well as quality management staff—all of whom are responsible to determine what corrective action, if any, is needed.[78]

The laboratory director and quality management technologist explained to the OIG why meeting minutes lack detail:

- The director stated variance reports are usually discussed more generally, without committee discussion of specific action items associated with the variance.
- The laboratory quality management technologist recalled that the CBC differential misreads were reported to the committee but with minimal feedback and explained the committee "doesn't necessarily look at the issues that arise for each variance."

The OIG found that the laboratory director and quality management technologist were not knowledgeable about the planned action to address inaccurate CBC with differential results from fall 2024. Specifically, the director could not recall discussing the variance report and the quality management technologist was unaware that additional competencies for the medical technologists remained incomplete in early spring 2025. The OIG would expect the laboratory director and quality management technologist, committee members responsible for the review and approval of variance reports, to have knowledge about this variance and the associated corrective actions given participation in committee meetings.[79]

The OIG also learned that the Quality Assurance Committee's reporting requirements and NEO's oversight do not include variance reporting. The laboratory quality management technologist told the OIG that although the Quality Assurance Committee reports quarterly data to the facility Integrated Clinical Council and the Healthcare Delivery Board (Council), the data does not include variance reports and is specific to metrics such as turnaround time, blood culture contamination rates, and wait times for the blood draw room.[80] The National PLM Quality and Compliance agent explained to the OIG that laboratories "can include" variance report data in quality metrics but reporting to the facility quality management service is not required.

Further, the OIG found laboratory leaders did not conduct an intensive investigation. The laboratory quality management technologist told the OIG that a variance investigation summary form was not completed for the inaccurate CBC with differential results from fall 2024 because

[78] Facility Policy GEN007. The laboratory quality management technologist told the OIG that, generally, laboratory leaders and supervisors attend the Quality Assurance Committee meetings.

[79] Facility Policy GEN007.

[80] VHA Directive 1159, *VHA Specialty Care Program Office and National Programs*, March 9, 2022. VHA identifies Integrated Clinical Communities as a "Veteran-centered operational clinical structure" to enable a rapid flow of information across VHA, between the field and through the Veterans Integrated Service Network and VHA Central Office; VHA, "Integrated Clinical Communities Implementation Frequently Asked Questions (FAQs)," November 8, 2019. The oversight body for all Integrated Clinical Committees is VHA National (Enterprise) Healthcare Delivery Council.

> [the more intensive investigation] is not clearly defined within the department, however when the magnitude of an error impacts accurate testing or impacts services outside of the laboratory, it would result in more intensive investigation.[81]

The OIG concluded that laboratory leaders did not follow policy to further investigate the variance of the fall 2024 inaccurate CBC with differential results, which precluded follow-up including the monitoring of corrective actions. The OIG determined that leaders did not follow policy, which contributed to delays in completing corrective actions and left patient safety risks unresolved.

4. Unsuccessful Proficiency Testing Performance in Blood Bank

The OIG substantiated that the off-tour supervisor did not pass a CAP blood bank proficiency test in June 2024, which led to the suspension of blood bank crossmatch testing services in July 2024.[82] The OIG found that the former laboratory director and the laboratory manager completed requirements to resume testing services, including investigating the circumstances that led to the unsuccessful proficiency test and completing related corrective actions.[83]

VHA requires that when CAP scores indicate a proficiency test as less than satisfactory, the laboratory director must "immediately investigate to determine the cause and take corrective action to maintain reliable patient testing performance."[84] VHA further requires 100 percent accuracy for blood bank crossmatch testing, and failure on a single test is considered unsatisfactory. When laboratory staff do not pass two out of three consecutive proficiency testing events in pretransfusion crossmatch testing, the laboratory director must cease testing on the instrument or method used.[85] The National PLM Quality and Compliance agent determines when services may resume, based on evidence that the laboratory director completed a satisfactory investigation, action plan, remedial testing, and verification of no immediate risk to patient health and safety.[86]

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[81] Facility Policy GEN007.

[82] Crossmatching is "the testing of the compatibility of the bloods of a transfusion donor and a recipient by mixing the serum of each with the red cells of the other to determine the absence of agglutination reactions." *Merriam-Webster.com Medical Dictionary*, "crossmatching," accessed May 13, 2025, https://www.merriam-webster.com/medical/crossmatching.

[83] VHA Directive 1106.

[84] VHA Directive 1106.

[85] VHA Directive 1106. Proficiency tests are shipped to the VA medical facility and include specimens for laboratory staff to analyze. Testing is performed on every instrument and method of patient testing and rotated among laboratory staff to ensure "equal frequency by all testing personnel." The blood bank supervisor told the OIG that testing is ceased when one medical technologist does not pass a proficiency test. Further, VHA Directive 1106 does not limit consecutive unsuccessful performances, over the three consecutive proficiency testing events to a single technologist.

[86] VHA Directive 1106.

The OIG found a laboratory medical technologist received a less than satisfactory score on a CAP blood bank proficiency test in 2023 but subsequently completed and passed the required repeat-testing.[87] Another crossmatch testing proficiency test, approximately one year later in June 2024, was assigned to the off-tour supervisor, who also received a less than satisfactory score.[88]

On July 17, 2024, the National PLM Quality and Compliance agent notified the laboratory director, via memorandum, that the blood bank failed two out of the three most recent proficiency events for crossmatch testing. According to VHA policy, laboratory staff must

- cease blood bank crossmatch testing,
- "immediately investigate the circumstances that" led to the proficiency testing failure,
- arrange for "remedial testing events" by a Centers for Medicare and Medicaid Services-approved provider, and
- submit testing results and supporting documentation of the "[i]nvestigation and narrative" to the National PLM Quality and Compliance agent for review and approval.[89]

During interviews, facility laboratory leaders reported complying with the requirements outlined in the memorandum and arranging a contingency plan for a local hospital to test patient specimens until the facility blood bank resumed crossmatch services.[90] The National PLM Quality and Compliance agent confirmed to the OIG that laboratory leaders complied with the proficiency testing failure protocol and resumed blood bank crossmatch services. The OIG reviewed a related issue brief that documented blood bank services resumed one week later, on July 24, 2024. The deputy chief of staff told the OIG there were no delays or canceled surgeries.

To address the off-tour supervisor's unsatisfactory proficiency test, the laboratory manager told the OIG of immediately removing the off-tour supervisor from blood bank duties and assigning repeat proficiency testing. The off-tour supervisor participated in additional training but was unsuccessful. Subsequently, the off-tour supervisor was detailed to a position outside of laboratory services and later resigned.[91] The laboratory manager reported that because of the proficiency testing incident, laboratory leaders have made process improvements regarding proficiency opportunities for medical technologists. Specifically, reducing the number of medical

[87] During an interview, the laboratory manager confirmed the medical technologist passed the repeat-testing. VHA Directive 1106.

[88] During an interview, the laboratory manager confirmed the supervisor did not pass the proficiency test or the refresher training.

[89] VHA Directive 1106.

[90] Facility laboratory leaders refer to the hematology medical director, the laboratory manager, and the blood bank supervisor.

[91] At the time of this inspection, the laboratory manager told the OIG of "covering [the] role" of the off-tour supervisor.

technologists on blood bank rotation to increase time spent in the blood bank for those individuals on the rotation. Additionally, the blood bank supervisor confirmed the use of new equipment for electronic crossmatch testing, which is expected to reduce errors.

The OIG concluded that facility laboratory leaders, upon learning of the unsatisfactory proficiency testing results, constructed a timely contingency plan to mitigate blood service disruptions and promptly completed VHA requirements to resume services. Further, laboratory leaders added process improvements to address proficiency needs and minimize potential for errors.

Conclusion

The OIG substantiated multiple medical technologists reported inaccurate CBC with differential results for the patient. However, the OIG did not identify adverse clinical outcomes related to these inaccuracies.

The OIG found none of the medical technologists involved in the inaccurate readings were aware of the errors prior to the OIG inspection. Although the hematology supervisor made corrections in the EHR upon learning of the inaccurate results, the supervisor did not provide individual feedback to staff who made the errors, which precluded mitigation of errors and limited proficiency improvement.

The OIG also found deficiencies in the laboratory quality assurance process to monitor the accuracy of blast identification. Specifically, despite knowledge of the medical technologists' errors in reading the patient's specimens in fall 2024, laboratory leaders had not implemented ongoing reviews of technologists' accuracy in cell identification. Until requested by the OIG, laboratory leaders did not conduct comprehensive retrospective reviews to determine whether other patients had inaccurate CBC with differential results or subsequent patient harm. The laboratory director reported that retrospective reviews will continue monthly to monitor and track the accuracy of results.

The OIG determined laboratory leaders, including the quality management technologist, as well as patient safety managers, did not ensure corrective actions were timely implemented, completed, or tracked. Laboratory leaders revised policy and completed additional competencies regarding medical technologists' CBC with differential readings; however, completion took almost six months from the time leaders were first aware of the inaccuracies. The OIG found the following factors contributed to delayed completion of corrective action and left patient safety risks unresolved:

- Patient safety managers did not ensure completion of action plans.
- The laboratory manager and quality management technologist had conflicting interpretations of the quality management technologist's role and responsibilities.

- Laboratory leaders did not follow a policy regarding variance reporting, including follow-up and assessing the effectiveness of the action taken.

The OIG also substantiated that the off-tour supervisor failed a CAP blood bank proficiency test in June 2024, which led to the suspension of blood bank crossmatch testing services in July 2024. However, the OIG determined laboratory leaders constructed a timely contingency plan to mitigate blood service disruptions and promptly completed VHA requirements to resume services. Further, laboratory leaders added blood bank process improvements to address proficiency needs and minimize potential for errors.

The OIG issued five recommendations to the Facility Director related to feedback to staff, patient safety, laboratory quality management, oversight of manual CBC with differential reads for accuracy, and corrective actions. The Acting Veterans Integrated Service Network and Facility Directors agreed with the findings and recommendations (refer to Appendixes A and B). In response, the Facility Director submitted implementation plans aimed at ensuring adherence to GEN031 (Competency Assessment Policy) and HEM017 (Resulting Sysmex XN-9199 Print-Offs for CBC with Differential). These plans involve supervisory staff reviewing identified errors with team members, incorporating lessons learned, and presenting updates during monthly quality assurance meetings.

To further support timely resolution of patient safety concerns, the Facility Director described processes for tracking and overseeing corrective action plans at the service level, managed through the Quality and Patient Safety (QPS) service. The Facility Director also reported that compliance checks are underway to confirm consistent application of a protocol for monthly retrospective secondary reviews conducted by pathologists.

Beginning in July 2025, the quality management technologist initiated formal reporting of internal error analyses and corresponding corrective actions during quality assurance meetings, in coordination with QPS and a patient safety analyst. The Facility Director also committed to ensuring that all supervisory personnel receive education on the quality management technologist's role and responsibilities.

Recommendations 1–5

1. The VA Detroit Healthcare System Director ensures pathology and laboratory medicine service leaders communicate feedback regarding staff-specific errors to facilitate staff learning and according to Veterans Health Administration high reliability organization guidance.

2. The VA Detroit Healthcare System Director evaluates the quality and patient safety service response to patient safety events, including tracking and monitoring of service level corrective action plans to ensure timely resolution of patient safety events, and takes action as necessary.

3. The VA Detroit Healthcare System Director verifies pathology and laboratory medicine service leaders demonstrate clear communication of the laboratory quality management technologist roles and responsibilities in accordance with Veterans Health Administration requirements.

4. The VA Detroit Healthcare System Director ensures the pathology and laboratory medicine service will sustain oversight of manual complete blood count with differential reads for accuracy via retrospective pathologist secondary reviews.

5. The VA Detroit Healthcare System Director makes certain that pathology and laboratory medicine service leaders track variance reporting and ensure completion of applicable corrective action in accordance with facility policy and Veterans Health Administration requirements.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: October 2, 2025

From: Acting Director, Veterans Integrated Service Network 10 (10N10)

Subj: VA Office of Inspector General (OIG) Draft Report—Evaluation of Specimen Readings for Accuracy and Quality Assurance in the Laboratory at the John D. Dingell VA Medical Center in Detroit, Michigan (VIEWS 13760619)

To: Director, Office of Healthcare Inspections (54HL07)
Chief Integrity and Compliance Officer (10OIC)

1. We appreciate the opportunity to work with OIG's Office of Healthcare Inspections as we continuously strive to improve the quality of health care for the Nation's Veterans. We are committed to ensuring Veterans receive quality care that utilizes the high reliability pillars, principles, and values. I concur with the report findings and recommendations of OIG draft report—Inaccurate Specimen Readings and Lapses in Quality Control in the Laboratory at John D. Dingell VA Medical Center in Detroit, Michigan.

2. I have reviewed the documentation and concur with the response as submitted by the Detroit VA Medical Center Director.

3. Should you need further information, contact the Veterans Integrated Service Network Acting Quality Management Officer.

(*Original signed October 3, 2025 by:*)

Beth Lumia, MSW

[OIG comment: The OIG received the above memorandum from VHA on October 3, 2025.]

Appendix B: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: October 2, 2025

From: Director, John D. Dingell Department of Veterans Affairs (VA) Medical Center (553)

Subj: VA Office of Inspector General (OIG) Draft Report—Evaluation of Specimen Readings for Accuracy and Quality Assurance in the Laboratory at the John D. Dingell VA Medical Center in Detroit, Michigan

To: Acting Director, Veterans Integrated Service Network 10 (10N10)

1. We appreciate the opportunity to review and comment on the OIG draft report— Inaccurate Specimen Readings and Lapses in Quality Control in the Laboratory at the John D. Dingell VA Medical Center in Detroit, Michigan. Veterans Integrated Service Network 10, concurs with the recommendations and will take corrective action.

2. I have reviewed the documentation and concur with the response as submitted.

3. Should you need further information, contact John D. Dingell VA Medical Center's Chief of Quality and Patient Safety Officer.

(*Original signed by*:)

Christopher Cauley, FACHE

[OIG comment: The OIG received the above memorandum from VHA on October 3, 2025.]

Facility Director Response

Recommendation 1

The VA Detroit Healthcare System Director ensures pathology and laboratory medicine service leaders communicate feedback regarding staff-specific errors to facilitate staff learning and according to Veterans Health Administration high reliability organization guidance.

_ X_Concur

____Nonconcur

Target date for completion: April 2026

Director Comments

The Associate Chief of Staff, Pathology and Laboratory Medicine (PLM) and PLM Manager reviewed GEN031 (Competency Assessment Policy) and HEM017 (Resulting Sysmex XN-9199 Print-Offs for CBC with Differential). These policies guide error assessment and the provision of timely feedback to staff. Policies GEN31 and HEM017 were discussed at the September 18, 2025, Quality Assurance (QA) meeting to review the sections that speak to competency assessment, retraining, and providing feedback to staff members when errors occur. PLM supervisors also review staff-specific errors directly with the applicable technologist to facilitate staff learning. Lastly, staff-specific errors are reported by the Quality Management (QM) Technologist at the monthly QA meeting, and supervisors are then responsible for communicating the errors and applicable lessons learned at their respective division huddles. Compliance will be measured through monitoring QA meeting minutes for the inclusion of staff-specific error reporting with a goal of 90%.

Recommendation 2

The VA Detroit Healthcare System Director evaluates the quality and patient safety service response to patient safety events, including tracking and monitoring of service level corrective action plans to ensure timely resolution of patient safety events, and takes action as necessary.

_ X_Concur

____Nonconcur

Target date for completion: April 2026

Director Comments

The Chief of Quality and Patient Safety (QPS) is responsible for management of patient safety events related to PLM. Joint Patient Safety Reporting (JPSR) events are processed following the

VHA National Center for Patient Safety JPSR Guidebook, dated December 2023. Each JPSR is reviewed and analyzed by the Patient Safety Manager (PSM). The PSM is also responsible for reviewing opportunities by producing reports from JPSR for data monitoring such as ongoing risks and trends; high frequency/low risk events or high risk/low frequency events; and areas of deficiency. The PSM analyzes this data to identify improvement actions. Improvement actions should be documented in JPSR by the event reviewer. JPSR follow-up and closure is monitored by the PSM. The number of JPSR action plans related to PLM that are closed timely (within 14 days) will be monitored and reported to the QPS Board until 90% compliance is achieved and maintained for 6 months.

Recommendation 3

The VA Detroit Healthcare System Director verifies pathology and laboratory medicine service leaders demonstrate clear communication of the laboratory quality management technologist roles and responsibilities in accordance with Veterans Health Administration requirements.

_ X_Concur

____Nonconcur

Target date for completion: December 2025

Director Comments

The Associate Chief of Staff, PLM and PLM Manager met with PLM supervisors on the roles and responsibilities of the QM Technologist. They reviewed the qualification standards in accordance with VHA requirements for the QM Technologist Series 0644. At the September 18, 2025, QA meeting, the QM Technologist functional statement was reviewed to ensure a more comprehensive understanding of the role and its impact within the department. The PLM Manager will review the QM Technologist role to clearly delineate responsibilities with the supervisors. Compliance will be demonstrated with 100% of supervisory staff being educated on the QM Technologist role and documented in an attestation statement.

Recommendation 4

The VA Detroit Healthcare System Director ensures the pathology and laboratory medicine service will sustain oversight of manual complete blood count with differential reads for accuracy via retrospective pathologist secondary reviews.

_ X_Concur

____Nonconcur

Target date for completion: December 2025

Director Comments

The Associate Chief of Staff, PLM has developed a protocol for monthly retrospective pathologist secondary reviews to be performed. This monthly review was implemented in February 2025. Monitoring will continue with monthly audits with a goal of 90% or greater compliance over 6 months.

Recommendation 5

The VA Detroit Healthcare System Director makes certain that pathology and laboratory medicine service leaders track variance reporting and ensure completion of applicable corrective action in accordance with facility policy and Veterans Health Administration requirements.

_ X_Concur

____Nonconcur

Target date for completion: April 2026

Director Comments

The QM Technologist and PLM leadership are responsible for reporting and tracking required PLM action items identified through internal variance reports. The QM Technologist sends an internal variance summary to the PLM leadership team daily. Effective July 2025, the QM Technologist began formal reporting of the analysis of internal errors through the monthly QA meeting where applicable corrective action is identified and assigned. The Chief of QPS and Patient Safety Analyst attends the QA meeting for collaboration and support. Compliance will be measured through monitoring QA meeting minutes for inclusion of internal error reporting and corrective action completion with a goal of 90% over 6 months.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Inspection Team	Alison Loughran, JD, BSN, Director David Allton, MD Debbie Davis, JD Ashley Dobrovech, MJ, RN Kristin Huson, LICSW, MSW Dannette Johnson, DO Deanna Lane, MSN Tanya Oberle, LCSW, MSW
Other Contributors	Shelby Assad, LCSW Carol Lukasewicz, BSN, RN Natalie Sadow, MBA

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