

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2174063	(X3) Date Survey Completed 05/20/2021
Name of Provider or Supplier Maryland Oncology Hematology P A	Street Address, City, State 20330 Seneca Meadows Parkway Suite B, Germantown, MD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical supervisor (TS), the laboratory failed to ensure that all testing personnel performing PT signed the PT attestation statements, attesting that PT specimens were run in the same way as patient samples. Findings: 1. At the time of the survey, the laboratory had 2 testing personnel listed on the "Laboratory Personnel Report (CMS-209)." 2. A review of hematology PT records for 4 PT events in 2020 and 2021 showed that for 3 of 4 events the testing person who performed the "Blood Cell Identification" and "Educational Blood Cell Identification" portion of the PT did not sign the attestation form. 3. This testing person was also not included on the "Laboratory Personnel Report (CMS-209)." 4. During an interview on 5/20/2021 at 2:30 PM, the TS confirmed that the attestation statements were not signed by all of the testing personnel performing PT.</p>
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p>

This STANDARD is not met as evidenced by:
Based on proficiency test (PT) record review and interview with the technical supervisor (TS), the laboratory failed to verify the accuracy of PT results which were not evaluated or scored by a CMS-approved PT program. Findings: 1. The laboratory participates in the hematology PT program, "Educational Blood Cell Identification". The PT provider provides an "Expected Result" but does not grade the PT performance. 2. A review of hematology PT records for 4 PT events in 2020 and 2021 showed that for 3 of 4 events the laboratory failed to perform a self-evaluation of "non-graded" results. 3. During an interview on 5/20/2021 at 2:30 PM, the TS confirmed that the laboratory did not evaluate PT results which were not graded by the PT provider to determine whether PT scores were acceptable.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation and interview with the technical supervisor (TS), the laboratory failed to label the Coplin jars with the stain reagent names, lot numbers and expiration dates. Findings: 1. The laboratory performed patient peripheral blood smears using the Astral Diagnostics Quick Stain reagent system. 2. While touring the laboratory, the surveyor observed three Coplin jars filled with staining reagents. None of the jars contained a label indicating the identity, the lot number, and the expiration date of each staining reagent. 3. During the exit interview on 05/20/2021 at 2:30 PM, the TS confirmed that the Coplin jars were not labeled with the identification, lot number, and expiration date of each staining reagent.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on record review and interview with the technical supervisor (TS) and testing person (TP), the laboratory failed to record stain quality control (QC) each day slides were prepared. Findings: 1. The laboratory performed patient peripheral blood smears using the Astral Diagnostics Quick Stain reagent system. 2. Daily stain QC was recorded on the log titled "MOH Wright Stain Daily Control Log", which contained columns labeled 1-31 for days of the month and 11 rows labeled with characteristics that are checked as part of the daily QC. 3. Each slide that was prepared was recorded on the monthly log titled "Slide Review Request Log", which contained the column labeled "Date Slide Stained." 4. The surveyor reviewed both the "MOH Wright Stain

Daily Control Log" and the "Slide Review Request Log" for the months of December 2019 through April 2021. During this time period, patient slides were prepared and stained on a total of 149 days. Of these 149 days, a total of 18 days were recorded in the "Date Slide Stained" column of the "Slide Review Request Log", but were not checked off on the respective dates on the "MOH Wright Stain Daily Control Log." 5. During the survey on 05/20/2021 at 1:15 PM, the TC and TP confirmed that not all dates recorded in the "Date Slide Stained" column of the "Slide Review Request Log" were checked off for daily QC performed on the "MOH Wright Stain Daily Control Log."