

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0878705	(X3) Date Survey Completed 06/09/2022
Name of Provider or Supplier Drs Chhabra & Sait, Md Pa	Street Address, City, State 3600 Leonardtown Road, Ste 101, Waldorf, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and patient testing logs and interview with the laboratory supervisor (LS), the laboratory failed to document urine and throat culture PT sample results in the same manner as routine patient specimen results in four of six testing events reviewed. Findings: 1. Urine culture and throat culture PT records for three events in 2020 and three events in 2021 were reviewed. 2. The laboratory recorded results of routine patient specimen urine and throat culture testing on separate logs. 3. Review of the urine culture and throat culture patient testing logs showed that PT sample results were logged with the patient specimen results on the 2020 1st and 2nd events but not the 2020 3rd event and all three 2021 events. 4. During the survey on 06/09/2022 at 2:00 PM, the LS confirmed that urine and throat culture PT sample results were not documented on routine patient specimen results logs for the 2020 3rd event and all three 2021 events.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in</p>

electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of the analyzer operator's manual and laboratory records and interview with the laboratory supervisor (LS), the laboratory failed to record humidity in the laboratory where hematology testing was performed. Findings: 1. The laboratory performed hematology testing using a CELL-DYN Emerald analyzer. 2. The analyzer operator's manual stated that relative humidity for instrument operation is less than 80%. 3. Laboratory records did not include documentation of humidity. 4. During the survey on 06/09/2022 at 2:00 PM, the LS confirmed that the laboratory was not recording humidity in the laboratory where hematology testing was performed.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) records and interview with the laboratory supervisor (LS), the laboratory director did not ensure that the corrective action plan for unacceptable hematology PT results included a review of patient results at the time of the unacceptable PT event. Findings: 1. The laboratory received a 60% for hemoglobin and a 77% for overall hematology in the 2021 1st PT event. 2. The investigation report did not include documentation of a review of patient results at the time of the unacceptable PT event and whether corrective actions were taken for patient results that may have been affected by the same issues that affected the unacceptable PT results. 3. During the survey on 06/09/2022 at 2:00 PM, the LS confirmed that the investigation report for the 2021 1st hematology PT event did not document whether patient results were affected by the same issues that affected the unacceptable PT results and what corrective actions were taken, if applicable.