

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D0934884	<b>(X3) Date Survey Completed</b>  09/13/2021
<b>Name of Provider or Supplier</b>  Glasgow Pediatric Healthcare	<b>Street Address, City, State</b>  301 Professional Pk, Glasgow, KY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2128</b>	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review of proficiency testing (PT) results from American Proficiency Institute (API) on 09/13/2021, the laboratory director failed to ensure proficiency test results were reviewed for two (2) out of three (3) events for 2020. The findings include: 1. Record review revealed the laboratory scored an overall ninety-six percent (96%) for Hematology and an eighty percent (80%) for the analyte Red Blood Cell Count (RBC) for API PT second (2nd) Event of 2020. Record review revealed the laboratory failed to document any corrective action for that event. 2. Record review revealed the laboratory scored an overall eighty percent (80%) for Hematology and an eighty percent (80%) for each of the analytes including RBC, White Blood Cell Count (WBC), Hemoglobin (Hgb), Hematocrit (Hct), Platelet Count (Plt) and White Blood Cell Identification (WBC ID) for API PT third (3rd) Event of 2020. Record review revealed that the laboratory failed to document any corrective action for that event. 3. The testing staff acknowledged in an interview at 10:20 AM. on 09/13/2021, that the laboratory director failed to establish a system to ensure proficiency testing results were evaluated.</p>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p>

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview on 09/13/2021, the laboratory failed to perform and document maintenance procedures as required and recommended by the manufacturers for the laboratory's microscope. The findings include: 1. Record review revealed the laboratory failed to perform weekly and monthly maintenance for the laboratory's microscope between 11/08/2019 and 09/12/2021. 2. Interview with laboratory staff at 9:10 AM on 09/13/2021 determined the laboratory failed to establish a system to ensure maintenance procedures were performed and documented as required and recommended by the manufacturer of the laboratory's microscope.

**D5807**

**TEST REPORT**  
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview on 09/13/2021, the laboratory failed to ensure the test report included a reference range for male and female patients for six (6) out of six (6) patients. , The findings include: 1. Record review of patient #1 on 07/28/2020 revealed the test report failed to include reference ranges for male and female patients. 2. Record review of patient #2 on 08/13/2020 revealed the test report failed to include reference ranges for male and female patients. 3. Record review of patient #3 on 09/15/2020, the test report failed to include reference ranges for male and female patients. 4. Record review of patient #4 on 12/30/2021 revealed the test report failed to include reference ranges for male and female patients. 5. Record review of patient #5 on 01/14/2021 revealed that the test report failed to include reference ranges for male and female patients. 6. Record review of patient #6 on 02/12/2021 revealed the test report failed to include reference ranges for male and female patients. 7. An interview with the staff at 9:05 AM on 09/13/2021 determined the laboratory director failed to establish a system to ensure the patient report included both male and female reference ranges.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on staff interview and record review on 09/13/2021, the Technical Consultant failed to perform and document annual competency using the six (6) mandated competency assessment requirements for testing personnel. Competency assessment

was not performed using six (6) methods of assessment for four (4) out of thirteen (13) testing personnel from 11/08/2019 through 09/12/2021. Findings include: 1. Record review on 09/13/2021 revealed there was no documented competency assessments between 11/08/2019 through 9/12/2021 for four (4) employees, who performed microscopic urinalysis, that included the following: competency assessments failed to include direct observation of routine patient test performance, direct observation of performance of instrument maintenance function checks and calibration, monitoring the recording and reporting of test results, review of worksheets, review of quality control records, review of proficiency test results, review of maintenance records, assessment of testing external proficiency testing samples and problem solving skills. 2. An interview with the staff on 09/13/2021 at 9:55 AM revealed the facility failed to have a system in place between 11/08/2019 through 09/12/2021 to ensure competency was performed using all six (6) mandated competency assessment requirements.