

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0306704	(X3) Date Survey Completed 08/13/2024
Name of Provider or Supplier Premier Medical Group	Street Address, City, State 490 Dunlop Lane, Clarksville, TN	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of the laboratory policy, laboratory personnel records, and staff interviews, the laboratory failed to follow the policy for competency assessment when the competency assessments did not contain all six required elements for testing personnel (19 of 19 reviewed) that performed vaginal potassium hydroxide (KOH), wet prep, fern testing, and urine colony count patient testing in 2023. The findings include: 1. Observation of the Obstetrics and Gynecology department laboratory on 08/12/2024 at 2:00 p.m. revealed KOH, saline, and a microscope used for patient Wet Prep, KOH, and Fern testing. 2. An observation of the laboratory in the Pediatric department on 08/13/2024 at 11:00 a.m. revealed Uricult media and an incubator used for patient urine colony count testing. 3. A review of the laboratory policy titled "Competency Assessment" revealed that personnel would be evaluated for competency through direct observation of patient test performance, monitoring the recording of patient test results, review of intermediate test results or worksheets, direct observation of performance or instrument maintenance, assessment through blind testing or proficiency testing samples, and assessment of problem-solving skills. 4. A review of the laboratory's personnel records revealed competency assessment documentation did not contain direct observation of patient test performance, monitoring of the recording of patient test results, review of intermediate test results or worksheets, direct observation of performance or instrument maintenance, or assessment of problem-solving skills for eight testing persons who performed wet prep, KOH, and fern testing in the OB laboratory and eleven testing persons who performed urine colony count testing in the</p>

Pediatric laboratory for 2023. 5. An interview with the technical consultant on 08/13 /2024 at 11:30 a.m. confirmed the laboratory failed to follow the policy for competency assessment for testing personnel that performed wet prep, KOH, fern, and urine colony count testing in 2023.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, laboratory procedure review, and staff interviews, the laboratory procedure for Complete Blood Count with White Blood Cell differential (CBCw/Diff) failed to include actions to take when patient CBC results obtained from the Sysmex XN 330 instruments were flagged. The findings include: 1. An observation of the laboratory on 08/12/2024 at 8:40 a.m. revealed two Sysmex XN 330 (Serial #s 11814 and 11822) instruments used for CBC patient testing. During the observation, the technical consultant stated the following: The Sysmex instrument reports "Positive" or "Negative" and displays any instrument flags. The instrument flags do not cross the interface to the patients' electronic chart and are not reported to the patients' provider. The laboratory does not have a policy for actions to take when CBC results are flagged. 2. A review of the laboratory procedure manual for CBC revealed that the procedure did not include instructions for CBC results that were "Positive" or contained flags. 3. An interview with the technical consultant on 08 /13/2024 at 11:30 a.m. confirmed the laboratory procedure manual failed to include instructions for actions to take when CBC w/Diff results obtained from the Sysmex XN 330 instruments were flagged.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as

acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on observation, record review, and staff interview, the laboratory failed to perform the six-month calibration verification for the Vitamin B12 analyte performed on the Ortho Vitros 5600 instrument when it was due in February 2024. The findings include: 1. An observation of the laboratory on 08/12/2024 at 8:40 a.m. revealed the Vitros 5600 (Serial 56004593) instrument used for patient testing for chemistry analytes. 2. A review of the laboratory's Vitamin B12 calibration and calibration verification records revealed the following: Calibrations were performed using a two-point calibration. Calibration verification was last performed on 08/02/2023. The records did not contain evidence that calibration verification was performed in February 2024. 3. An interview with the technical consultant on 08/13/2024 at 11:30 a.m. confirmed that the laboratory tested 1,641 patients for the Vitamin B12 analyte between February 2024 and the date of the survey (08/13/2024) and failed to perform the required calibration verification in February 2024.