

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0179384	(X3) Date Survey Completed 07/18/2023
Name of Provider or Supplier Upmc Hcc Passavant, Upmc Magee	Street Address, City, State 9100 Babcock Blvd, Pittsburgh, PA	
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 review of the laboratory's competency assessment records, and interview with the laboratory manager (LM), the laboratory failed to establish and follow written policies and procedures to assess the competency of 1 of 1 technical supervisor (TS) for their supervisory responsibilities listed in Subpart M from 01/01/2021 through the time of the survey. Findings Include: 1. On the day of the survey, 07/18/2023 at 12:00 pm, the laboratory could not provide a competency assessment procedure to assess the competency of 1 of 1 TS (CMS personnel # 4) for their supervisory responsibilities listed in Subpart M from 01/01/2021 to 07/18/2023. 2. The laboratory could not provide records of competency assessments performed for 1 of 1 TS from 01/01/2021 to the date of the survey. 3. The LM interviewed on 7/18/2023 around 01:00 pm confirmed the findings above.</p>
D5405	<p>PROCEDURE MANUAL CFR(s): 493.1251(c)</p> <p>Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the Beckman Coulter DxH 520 operator manual and interview with the laboratory manager (LM), the laboratory failed to have a complete written procedure manual for Complete Blood Count (CBC) testing that met the requirements of 493.1251 from 01/01/2021 to the date of the survey. Findings include: 1. On the day of the survey, 7/18/2023 at 11:00 AM, review of the Beckman Coulter DxH 520 operators manual revealed that the test system instructions used to perform CBC's failed to include the following requirements of 493.1251 from 01/01/2021 to 07/18/2023: - Step by step performance of the procedure including test calculations and interpretation of results - Preparation of slides, solution, calibrators, controls, reagents, stains, and other material used in testing. - Control procedures - Corrective action to take when calibrations or control results fail to meet the laboratory criteria for acceptability 2. The LM confirmed the findings on 7/18/2023 at 1:30 PM.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
 CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
 Based on review of the Beckman Coulter DxH 520 analyzer validation records and interview with the laboratory manager (LM), the laboratory failed to provide complete validation records for the required performance specifications for 13 of 13 analytes tested on the Beckman Coulter DxH 520 analyzer before reporting patient results from 01/01/2021 to the date of the survey. Findings Include: 1. On the day of survey, 07/18/2023 at 12:44 pm, the laboratory could not provide documentation of a reference range/normal value study appropriate for the laboratory's patient population for the following 13 of 13 hematology analytes performed on the Beckman Coulter DxH 520 from 01/01/2021 to 01/18/2023: - White Blood Count (WBC) - Red Blood Count (RBC) - Hemoglobin (HGB) - Hematocrit (HCT) - Mean Corpuscular Volume (MCV) - Mean Corpuscular Hemoglobin (MCH) - Mean Corpuscular Hemoglobin Concentration (MCHC) - Platelet (PLT) - Neutrophils (NEU) - Lymphocytes (LYM) - Monocytes (MON) - Eosinophils (EOS) - Basophils (BAS) 2. The laboratory could not provide documentation for the following validation studies on the Beckman Coulter DxH 520 analyzer: -Sodium Citrate (blue top tubes) used for platelet clumping 3. The LM confirmed the findings above on 07/18/2023 around 01:30 pm.

D5447

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of quality control (QC) records and interview with the laboratory manager (LM), the laboratory failed to include two control materials of different concentrations for microscopic urinalysis examinations at least once each day of patient testing from 01/01/2021 to the date of survey. Findings include: 1. On the day of survey, 07/18/2023 at 11:15 am, review of the microscopic urinalysis QC records revealed the laboratory performed 2 of 2 levels of external quality controls (MAS UA QC) for microscopic urinalysis examinations weekly from 01/01/2021 to 07/18/2023. 2. The laboratory performed 348 urinalysis examinations in 2022 (CMS 116 annual volume). 3. The LM confirmed the findings above on 7/18.2023 at 1:30 PM.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's quality control (QC) records and interview with the laboratory manager (LM), the laboratory failed to provide documentation of the corrective actions taken when 9 of 21 days of QC results failed to meet the laboratory's established acceptable criteria for complete blood count (CBC) testing performed on the Beckman Coulter DxH 520 in November 2022. Findings Include: 1. On the day of survey, 07/18/2023 at 11:36 AM, a review of the laboratory's CBC QC logs revealed the abnormal (low) level of QC for the following 9 of 21 days failed to meet the laboratory's established acceptable criteria for CBC testing (Mean Platelet Volume) performed in November 2022: - 11/02/2022 - 11/08/2022 - 11/11/2022 - 11/16/2022 - 11/17/2022 - 11/18/2022 - 11/23/2022 - 11/25/2022 - 11/30/2022 2. The laboratory could not provide documentation of corrective actions taken for QC performed on the Beckman Coulter DxH 520 that did not meet the laboratory's established acceptable criteria. 3. The LM confirmed the findings above on 07/18/2022 at 1:30 PM.