

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0999301	(X3) Date Survey Completed 03/07/2024
Name of Provider or Supplier Upmc Hcc Mt Pleasant-Upmc Magee	Street Address, City, State 508 South Church Street, Suite 202, Mount Pleasant, 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
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with technical supervisor #2 (TS), the laboratory failed to establish performance specifications before reporting patient test results when modifying an FDA-cleared/approved test system for platelet (PLT) counts performed on the DXH 520 from 06/07/2022 to 03/07/2024. Findings include: 1. The laboratory's procedure for EDTA clumping states, "If platelet clumps are observed on the smear the specimen should be recollected in sodium citrate anticoagulant (blue top tube). Reanalyze the specimen for platelet count only and multiply the result by 1:1. Peripheral smears will be made on both blue top and lavender top for platelet count review and verification." 2. Review of the DXH 520 manufacturer's instructions lists only EDTA K2 and EDTA K3 as acceptable anticoagulants and states, "Beckman Coulter neither recommends the use of one sample tube in preference to another nor guarantees the acceptability of the sample tube to produce quality results." 3. On the day of the survey, 03/07/2024 at 02:46 pm, the laboratory could not provide documentation for the performance</p>

specifications established when performing PLT counts using sodium citrate anticoagulant (blue top tube) for 1 of 1 DXH 520 analyzer from 06/07/2022 to 03/07/2024. 4. TS #2 confirmed the findings above on 03/07/2024 at 4:15 pm.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(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--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on lack of quality control (QC) records and interview with the technical supervisor #2, the laboratory failed to document a negative and positive control material each day of patient testing for microscopic urinalysis examinations performed in 2022 and 2023. Findings Include: 1. On the day of the survey, 03/07/2024 at 02:02 pm, the laboratory failed to provide documentation for the positive and negative QC performed each day of testing for the following 2 of 6 urine microscopic analytes: Microscopic urinalysis- Epithelial Cells. Microscopic urinalysis - Bacteria. 2. The laboratory performed 33 microscopic urinalysis examinations testing in 2023. 3. TS #2 confirmed the findings above on 03/07/2024 at 04:15 pm.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with technical supervisor #2, the laboratory failed to evaluate twice a year the relationship between test results using different methodologies for hematology examinations performed in 2022 and 2023. Findings include: 1. On the days of survey, 03/07/2024 at 03:45 pm, the laboratory failed to provide documentation of the biannual comparison studies performed in 2022 and 2023 for the following hematology examinations: --White blood cell differentials: manual microscopic vs. automated (DXH 520) 2. TS#2 confirmed the findings above on 03/07/2024 at 04:15 pm.