Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1048508	01/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Meritus Urgent Care, Llc	13620 Crayton Blvd, Hagerstown, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the hematology proficiency testing (PT) records and interview with the technical consultant, the laboratory did not ensure that the all PT records identified who tested each of the PT specimens. Findings: 1. The PT records from the 2017 and 2018 (6 events) were reviewed. 2. The PT attestation sheet from 2017 M-3 showed that there were 3 testing personnel signatures. The instrument printouts did not have any signatures. There was no way to identify who performed each of the 5 PT specimens tested. 3. The PT attestation sheet from 2017 M-2 showed that there were 3 testing personnel signatures. The instrument printouts did not have any signatures. There was no way to identify who performed each of the 5 PT specimens tested. 4. The PT attestation sheet from 2018 M-2 showed that there were 5 testing personnel signatures. The instrument printouts did not have any signatures. There was no way to identify who performed each of the 5 PT specimens tested. 5. During the survey on 01/29/2019 at 11:30 AM the technical consultant confirmed that the PT records did not identify which testing person performed each of the PT samples for the events listed above.

D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) records and interview with the technical consultant, the laboratory's QA program did not include a post analytical system to ensure that the testing personnel were informed of QA reviews conducted by the technical consultant and lead testing person and reviewed and signed by the laboratory director. Findings: The technical consultant stated that she performed a QA review on a monthly basis and documented the findings on a monthly worksheet for the lead testing person and laboratory director to review. The QA plan did not include a system for communicating the findings of the monthly QA review to the testing personnel to ensure that problems and corrective actions are discussed with the staff members as a part of an ongoing in-service program.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on review of the Levy-Jennings (L-J) graphs and interview with the technical consultant, the technical consultant did not ensure that remedial actions were documented when the quality control (QC) results for the level 1 hemoglobin control showed a shift taken of one standard deviation (SD) above the mean in 2017. Findings: 1. The L-J graphs for 2017 through 2018 were reviewed. The printouts for 04/08/17 through 04/29/17; 05/10/17 through 05/31/17; 05/31/17 through 06/30/17; 07 /05/17 through 07/31/17; 08/07/17 through 08/31/17; and 09/02/17 through 09/25/17 showed that the hemoglobin QC results for level 1 had shifted to a new mean of 1 SD above the listed mean. 2. The technical consultant stated that they were aware of the shift in the mean but did not document the evaluation showing that this shift would not affect patient test results. 3. During the survey on 01/29/2019 at 11:30 AM the technical consultant confirmed that the hemoglobin QC for Level one had shifted but the laboratory did not document the evaluation showing that this shift did not affect patient test results.