

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2002626	(X3) Date Survey Completed 07/06/2022
Name of Provider or Supplier Assoc In Hematology-Oncology	Street Address, City, State 213 Reeceville Road, Coatesville, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with laboratory supervisor (LS), the laboratory failed to have a written procedure manual for the Hematology Complete Blood Count (CBC) , Calibration and Calibration Verification performed. Findings include: 1. On the date of survey, 07/06/2022 at 11:15 am, the laboratory was unable to provide a procedure for the CBC, Calibration and Calibration Verification. 2. The laboratory supervisor confirmed during an interview on 07/06/2022 at 12:20 pm, that the laboratory did not have a written procedure for the above tests performed.</p>
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:

Based on lack of documentation, and interview of the laboratory supervisor (LS), it was determined that the laboratory did not maintain their quality control (QC) records to adequately monitor the accuracy and precision of each tests performance. Findings include: 1. On the day of survey 07/06/2022 at 1041am, the laboratory failed to produce daily documentation of corrective action taken for any out of range QC results for Hematology Complete Blood Count (CBC) from 6/30/2020 to 07/06/2022. 2. The LS confirmed the findings above on 07/06/2022 at 12:15pm.