

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D2002626	<b>(X3) Date Survey Completed</b> 06/30/2020
<b>Name of Provider or Supplier</b> Assoc In Hematology-Oncology	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based upon a review of proficiency testing records and interview with the Laboratory Supervisor, on the date of the survey (06/30/2020), the Laboratory Director failed to sign the College of American Pathologists (CAP) Attestation Statement, for CAP Hematology FH1-C-2019 proficiency test. The (CAP) Attestation Statements, was 1 of 6 CAP testing events from 2018 through the end of 2019. Findings: 1. At the time of the survey, (09:15 06/30/2020), 1 of 6 CAP testing event attestation statements reviewed (CAP Hematology FH1-C-2018), did not have the Laboratory Director's signature. 2. Testing events reviewed include: CAP Hematology FH1-C-2018 1st event, CAP Hematology FH1-C- 2018 2nd event, CAP Hematology FH1-C- 2018 3rd event, CAP Hematology FH1-C- 2019 1st event, CAP Hematology FH1-C- 2019 2nd event, and CAP Hematology FH1-C- 2019 3rd event. 3. During the survey (11:30 06 /30/2020), the Laboratory Supervisor confirmed the above findings. Hematology FH1-C-2018 proficiency test review</p>
<b>D5401</b>	PROCEDURE MANUAL

CFR(s): 493.1251(a)

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.

This STANDARD is not met as evidenced by:

Based on personnel interview of the Laboratory Manager and the General Supervisor and review of the laboratory procedure manual in use on the date of the survey (06/30/2020), the procedure manual failed to include all procedures required by 493.1251 (b). Findings include: 1. The procedure manual in use on the date of the survey (06/30/2020), did not include a description of the course of action, for reporting test results when results exceed the laboratory's reportable range. 2. During the survey (11:30 04/04/2019), the General Supervisor confirmed the above finding.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of proficiency test records and interview with the Laboratory Supervisor on the date of the survey (06/30/2020), the Laboratory Director failed to ensure that all proficiency testing reports received were reviewed by appropriate staff from 2018 through the end of 2019. Findings include: 1. The Laboratory Director failed to sign the CAP Hematology FH1-C-2018 proficiency test review. 2. The CAP Hematology FH1-C-2018 proficiency test review, was signed by the Laboratory Supervisor who only held the Clia Laboratory Testing Personnel position. 3. Corrective action was not documented for 1 of 6 proficiency test events with an unsatisfactory Hematocrit score of 40%. 4. During the survey (11:30 06/30/2020), the Laboratory Supervisor confirmed that the Laboratory Director did not sign the CAP Hematology FH1-C-2018 proficiency test review.