

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2314273	(X3) Date Survey Completed 05/21/2025
Name of Provider or Supplier Vinodh Pillai	Street Address, City, State 1236 Green Tree Lane, Penn Valley, 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
D0000	An initial survey was conducted by the Pennsylvania State Agency at Vinodh Pillai Laboratory on 05/21/2025. The laboratory was found out of compliance with the following condition: 493.801 Condition: Enrollment and testing of samples.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to enroll in an HHS approved proficiency testing (PT) program for Cell Identification (hematology) from 11/18/2024 to 05/21/2025. Findings include: 1. On the date of the survey, 05/21/2024, the laboratory failed to provide documentation for the enrollment in an HHS approved PT program for Cell Identification (hematology) from 11/18/2024 to the date of the survey. 2. The LD confirmed the above findings on 5/21/2025 at 9:41 am.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems</p>

identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with the Laboratory Director (LD), the laboratory failed to establish a quality assessment (QA) policy for monitoring, assessing, and correcting problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236 for 6 of 6 months that testing was performed from 11/18/2024 to the date of the survey. Findings include: 1. On the day of the survey, 5/21/2025, the laboratory failed to provide a written QA policy for the ongoing monitoring, assessing, and correcting problems in the general laboratory systems requirements specified at 493.1231 through 493.1236 for 6 of 6 months that testing was performed from 11/18/2024 to the date of the survey. 2. The LD confirmed the above findings on 5/21/2025 at 9:41 am.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

(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 lack of documentation and interview with the Laboratory Director (LD), the laboratory failed to provide an approved procedure manual for any aspect of hematology and histopathology microscopic examinations performed from 11/18/2014 to 05/21/2025. Findings Include: 1. On the day of the survey, 5/21/2025, interview with the LD and lack of documentation revealed the laboratory failed to provide an approved procedure manual for any aspect of hematology and histopathology microscopic examinations performed from 11/18/2014 to 05/21/2025. 2. The LD confirmed the above findings on 5/21/2025 at 9:41 am.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with the Laboratory Director (LD), the laboratory failed to monitor and document temperature and humidity to ensure proper test system operating conditions were met for 1 of 1 Olympus BX40 microscope used to perform hematology and histopathology microscopic examinations from 11/18

/2024 to 05/21/2025. Findings include: 1. On the day of the survey, 5/21/2025 the laboratory failed to provide documentation for the relative humidity (acceptable range: 30-90%) and room temperatures (acceptable range: 0 to 40 degrees Celsius) taken from 11/18/2024 to 05/21/2025 to ensure operating conditions were met for 1 of 1 Olympus BX40 microscope (s/n:4H07072) used for microscopic slide examinations (hematology/histopathology). 2. The LD confirmed the above findings on 05/21/2025 at 9:41 am.