

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0890209	(X3) Date Survey Completed 05/27/2026
Name of Provider or Supplier Satish A Shah Md Laboratory	Street Address, City, State Gettysburg Cancer Center, Gettysburg, 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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on lack of documentation, and interview with Testing Personnel (TP) #1, the laboratory failed to document the Quality Control (QC) performed for 1 of 3 chemistry tests performed from 4/29/2024 to 5/27/2026: Findings include: 1. On the day of the survey, 5/27/2026, the laboratory failed to provide documentation of QC performed for the following 1 of 3 chemistry tests performed from 4/29/2024 to 5/27/2026: - Fingerstick Blood Glucose: Contour (Manufacturer's requirement- "You should perform a control test when using your meter for the first time, when you open a new package of test strips, if you think your meter may not be working properly, or if you have repeated, unexpected blood glucose results".) 2. Review of laboratory records revealed the laboratory performed the following examinations from 4/29/2024 to 5/27/2026: - 6 Fingerstick Blood Glucose 3. TP #1 confirmed the findings above on 5/27/26 at 12:45 pm.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with Testing Personnel (TP) #1, the Technical Consultant (TC) failed to perform the competency assessments (CA) for 9 of 9 TP that performed hematology examinations in 2025. Findings

Include: 1. The laboratory's CLIA Quality Management Policy stated, "Competency Evaluations: 1) Employees responsible for nonwaived testing in Satish A. Shah Laboratory will not perform testing until they have been certified by the laboratory director as being competent to perform testing. 2) Competency will be evaluated at least semiannually during the first year the employee tests patient specimens. 2a) Thereafter, evaluations will be performed every six (6) for each laboratory test a person performs." 2. On the day of survey, 05/27/2026 at 10:15 am, the laboratory failed to provide CA records for 9 of 9 TP (CMS 209, TP#1, TP#2, TP#3, TP#4, TP#5, TP#6, TP#7, TP#8, TP#9, dated 5/11/2026), that performed complete blood count (CBC) examinations in 2025. 3. The laboratory performed 34,716 CBC examinations in 2025 (CMS 116, estimated annual volume, dated 5/11/2026). 4. TP#1 confirmed the above findings on 5/27/2026 at 12:45 pm.