

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2044746	(X3) Date Survey Completed 11/02/2022
Name of Provider or Supplier Satish A Shah Md Laboratory-Hanover Cancer Ctr	Street Address, City, State 195 Stock St, Suite 304, Hanover, 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
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the competency assessment (CA) records and interview with the Laboratory Director (LD), the TC failed to assess the competency of 2 of 13 testing personnel (TP) who performed the Complete Blood Count (CBC) test from 9/24/2020 to 11/02/2022. Findings Include: 1. On the day of the Survey, 11/02/2022 at 11:40 AM, a review of the competency assessment records revealed, TP #1 (CMS 209) missing competency assessment for 2021 and TP #7 (CMS 209) missing 6 month's competency assessment (hired on June 2021) who performed CBC tests in 2021 and 2022. 2. The LD confirmed the finding above on 11/002//2022 at 12:46 PM.</p>
D6051	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency assessment records and interview with Laboratory Director (LD), the Technical Consultant (TC) failed to evaluate the test performance of 12 of 13 testing personnel (TP) through internal blind testing samples or external Proficiency Testing (PT) samples for Complete Blood Count (CBC) assay</p>

examinations from 09/24/2020 to 11/02/2022. . Findings Include: 1. At the time of survey, 11/02/2022 at 11:43 AM, a review of the competency assessment records revealed, the laboratory failed to establish a procedure to assess test performance of 12 of 13 TP through internal blind testing samples or external PT samples from 2020 to 2022 who performed CBC examinations on the Medonic M series analyzer. 2. A review of 12 of 13 TP competency assessments revealed that they were missing the following point "Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples;" 3. The LD confirmed the findings above on 11/02/2022 around 12:46 PM.