

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2077410	(X3) Date Survey Completed 02/26/2020
Name of Provider or Supplier Wayne Memorial Hamlin Laboratory	Street Address, City, State 543 Easton Turnpike Suite 105, Lake Ariel, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, interview with the laboratory manager and technical consultant (TC) #2, the laboratory failed to establish a complete competency assessment policy to assess the competency of 1 of 2 TCs and 4 of 4 testing personnel (TP) in 2018 to the day of survey. Findings Include: 1. On the day of survey, 02/26/2020, the laboratory failed to provide a complete competency assessment policy to assess the competency of 1 of 2 TC and 4 of 4 TP from 01/10/2018 to 02/26/2020. 2. The laboratory manager and TC #2 confirmed the finding above on 02/26/2020 around 10:00 am.</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 testing personnel (TP) records, review of the American Proficiency Institute (API) 2018 and 2019 proficiency testing (PT) attestation sheets, interview with the laboratory manager and technical consultant (TC) #2, the TC failed to assess the competency of 2 of 4 TP through external hematology PT or internal</p>

blind testing samples in 2018 and 2019. Findings Include: 1. On the day of survey, 02/26/2020, review of TP records and API PT attestation sheets revealed, the laboratory did not assess the test performance of 2 of 4 TP (on the CMS 209 Testing Personnel Form - TP #1 and #4) thorough hematology PT samples or internal blind testing samples in 2018 and 2019. 2. The laboratory manager and TC #2 confirmed the finding above on 02/26/2020 around 10:30 am.