

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0214196	<b>(X3) Date Survey Completed</b>  07/29/2021
<b>Name of Provider or Supplier</b>  Harford Primary Care Llc	<b>Street Address, City, State</b>  615 West Mac Phail Road Suite 106, Bel Air, MD	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 competency assessment record review and interview with the technical consultant (TC), the laboratory did not establish written policies and procedures for assessing the competency of the TC based on the position responsibilities listed in Subpart M- CFR 493.1413. Findings: 1. A review of competency assessment records from 2019 and 2020 showed that at the time of the survey there was no competency assessment available for the TC. 2. In an email from 7/12/2021 the TC stated, "I do not have a competency assessment from the lab director." 3. During a phone interview on 7/29/2021 at 9:15 AM, the TC confirmed that the laboratory director had not performed a competency assessment on the TC.</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual and laboratory reagent package insert review and interview with the technical consultant (TC), the laboratory did not follow the</p>

manufacturer's requirements for performing bacteriology testing. Findings: 1. During a phone interview on 5/3/2021 at 1:30 PM, the TC stated that the laboratory is performing presumptive identification of group A streptococcus on throat cultures, using Taxo A discs which are impregnated with low levels of Bacitracin. The TC stated that the laboratory evaluated the culture plates at 24 and 48 hours after inoculation. 2. Review of the package insert for the "BD BBL Taxo A Discs" showed that culture plates must be incubated "at 35 to 37 degrees C for 18 to 24 hours" before being read or interpreted. 3. The TC confirmed that the laboratory's written procedure for performing throat cultures did not follow the manufacturer's requirements and that they would update the procedure.