

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0860076	(X3) Date Survey Completed 10/01/2025
Name of Provider or Supplier Healthstar Physicians Pc	Street Address, City, State 150 West Price Rd, Dandridge, TN	
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 a review of the Laboratory Personnel Report (CLIA) Form CMS 209 (Form CMS 209), review of laboratory procedures, and an interview with the technical consultant (TC), the laboratory failed to establish a competency assessment procedure that included the assessment of the regulatory responsibilities for the technical consultant (TC) on the survey date (10.01.2025). Findings Included: 1. A review of Form CMS 209, signed by the laboratory director on 10.01.2025, listed one TC for the laboratory. 2. A review of the laboratory procedures revealed no competency assessment procedure that included the assessment of the regulatory responsibilities for the TC was available for surveyor review. 3. An interview with the TC on 10.01.2025 at 11:00 a.m. confirmed the above findings.</p>
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or</p>

she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's personnel records and staff interview, the laboratory director failed to delegate technical consultant (TC) responsibilities in writing and to perform competency assessments for the TC in 2023 and 2024. The findings include: 1. A review of the laboratory's personnel records revealed the following: -No written delegation from the laboratory director for the TC regulatory responsibilities was available for the surveyor's review. - No annual TC competency assessment documentation by the laboratory director was available for 2023 and 2024. 2. An interview with the TC on 10.01.2025 at 11:00 a.m. confirmed the above findings.