

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1107858	(X3) Date Survey Completed 12/10/2025
Name of Provider or Supplier York Hosp Pulm Physiology Lab	Street Address, City, State 2350 Freedom Way Suite 201, York, 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
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with Technical Consultant (TC) #2 (CMS 209, dated 12/08/2025), the laboratory failed to establish and maintain written policies for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the postanalytic systems specified in 493.1291 for 2 of 2 years from 2/29/2024 to 12/10/2025. Findings include: 1. On the day of survey, 12/10/2025 at 11:59 am, the laboratory could not provide a procedure for the ongoing mechanism to monitor, assess, and correct problems found in the postanalytic system specified in 493.1291 for 2 of 2 years from 2/29/2024 to 12/10/2025. 2. The laboratory failed to provide records for the following periodic checks performed to verify the accuracy of the Laboratory's Information System (LIS) from 2/29/2024 to 12/10/2025: - Patient results transmitted between instruments and LIS (EPIC) - Patient Specific data. 3. The laboratory performed 224 Blood Gas examinations in 2024 (CMS 116, estimated annual volume, dated 12/08/2025). 4. TC #2 confirmed the findings above on 12/10/2025 at 1:45 pm.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and</p>

This STANDARD is not met as evidenced by:
Based on review of the laboratory's proficiency testing (PT) results from the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE), lack of documentation and interview with Technical Consultant (TC) #2 (CMS 209, dated 12/08/2025), the laboratory director (LD) failed to ensure that all PT reports received were reviewed by the appropriate staff to evaluate and identify problems that required corrective action for 1 of 1 AAB-MLE PT testing event for Chemistry in 2025. Findings include: 1. On 12/10/2025, at 11:36 am, review of 1 of 1 AAB-MLE PT reports revealed the laboratory failed to provide documentation for the corrective action taken for the following PT results obtained in 2025: - pH-Blood Gas (80%): Spec 6: Out of grading range or incorrect response. 2. The laboratory failed to provide a comprehensive policy for the PT testing performance and evaluation performed by the laboratory in 2025. 3. TC #2 confirmed the findings above on 12/10/2025 at 1:45 pm.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with Technical Consultant (TC) #2 (CMS 209, dated 12/08/2025), the Laboratory Director failed to ensure a Quality Assessment (QA) program was established and maintained to assure the quality of laboratory services provided and to identify failures in quality for blood gas examinations performed for 2 of 2 years from 02/29/2024 to the day of survey. Findings include: 1. On the day of the survey, 12/10/2025 at 11:59 am, the laboratory failed to provide a QA procedure for blood gas examinations performed for 2 of 2 years from 02/29/2024 to 12/10/2025. 2. The laboratory performed 224 Blood Gas examinations in 2024 (CMS 116, estimated annual volume, dated 12/08/2025). 3. TC #2 confirmed the findings above on 12/10/2025 at 1:45 pm.