

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0361904	(X3) Date Survey Completed 03/04/2026
Name of Provider or Supplier Terre Haute Reg Hosp Resp Care Dept	Street Address, City, State 3901 S 7th St, Terre Haute, IN	
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
D0000	An on-site validation survey was conducted on March 04, 2026 with the following standard level deficiencies cited.
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's policy, the laboratory's submitted Centers for Medicare and Medicaid Services (CMS) 209 Form, personnel records, and interview with Technical Consultant (TC) #2, according to the CMS 209 Form, the laboratory failed to establish and follow a policy for Testing Personnel (TP) and consultant competency assessment for one of two Technical Consultants. Findings Included: 1) Review of the laboratory's written policies and procedures did not reveal components of monitoring competency of TPs and consultants as required. 2) Review of the CMS 209 Form revealed two individuals in the TC role between 2024 and 2025. 3) Review of personnel records indicated the laboratory failed to provide documentation of consultant competency assessment for TC #1. 4) In an interview at 12:30 PM in the meeting room, TC#2 confirmed the inability to retrieve documentation of TC#1s competency assessment.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform</p>

test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on direct observation, policies and procedures, and interview with Technical Consultant (TC) #2, according to the Centers for Medicare and Medicaid Services (CMS) Form 209, the laboratory director (LD) failed to ensure that policies and procedures were established for monitoring the competency on the Radiometer ABL 90 Flex Plus analyzer of testing personnel (TP) and consultants for two of two years (2024 and 2025). Findings Included: 1. During a laboratory tour at 10:00 AM, the following instruments were observed in use for testing: a. Radiometer ABL 90 Flex Plus, Serial Number: 092R0295N066, Located in the Intensive Care Unit (ICU) b. Radiometer ABL 90 Flex Plus, Serial Number: 092R0295N067, Located next to Respiratory Department c. Radiometer ABL 90 Flex Plus, Serial Number: 092R0295N068, Located in the Operating Room (OR) 2. Review of the laboratory's written policies and procedures failed to include components of monitoring competency of TPs and consultants, as required (Refer to D5209). 3. In an interview at 12:30 PM in the meeting room, TC #2 confirmed the policies and procedures did not contain elements of monitoring competency of TPs and consultants.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted Centers for Medicare and Medicaid Services (CMS) 209 Form, laboratory's personnel records, and interview with the Technical Consultant (TC) #2, according to the CMS 209 Form, TC #2 failed to ensure documentation of annual competency evaluation for nine of nine testing personnel (TP). Findings Included: 1) Review of the CMS 209 form revealed nine TPs performing moderate complexity testing on the Radiometer ABL 90 Flex Plus analyzer. 2) Review of the laboratory's personnel competency records revealed cover sheets of staff training and competency evaluation, signed by the Laboratory Director, but no substantiating documentation provided of the six required procedural elements of competency assessment activities performed (e.g., Routine test performance, recording and reporting of test results, reviewing test results and quality control records, performance of instrument maintenance and function checks, assessing test performance with previous or blind testing samples, assessing problem solving skills). 3) In an interview at 11:30 AM in the meeting room, TC #2 confirmed the lack of personnel competency documentation.