

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1050690	(X3) Date Survey Completed 08/11/2026
Name of Provider or Supplier Northern Tier Research	Street Address, City, State 1302 Madison Ave, Dunmore, 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	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Laboratory Director (LD), the laboratory failed to establish and follow a competency assessment (CA) procedure to assess the competency of 3 of 3 General Supervisors (GS) for their supervisory responsibilities performed from 09/17/2024 to 08/11/2026. Findings Include: 1. On the day of survey, 08/11/2026 at 11:30 am, the laboratory failed to provide a competency assessment procedure to assess the competency of 3 of 3 GS (CMS 209, GS # 1, 2 and 3, dated 08/11/2026) for their supervisory responsibilities performed in the laboratory from 09/17/2024 to 08/11/2026. 2. The laboratory failed to provide CA records for GS #1, 2 and 3 for their supervisory responsibilities performed from 09/17/2024 to 08/11/2026. 3. The LD confirmed the findings above on 08/11/2026 at 1:45 pm.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test

	reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature logs, lack of documentation and interview with the Laboratory Director (LD), the laboratory failed to monitor and document room humidity (RH) as required to ensure reliable test system operation and test result reporting for 4 of 4 instruments used to perform Chemistry/Toxicology testing from 09/17/2024 to date of survey. Findings include: 1. On the date of the survey, 08/11/2026 at 1:00 pm, review of the laboratory's temperature logs revealed the laboratory failed to document room humidity (RH) to ensure operating conditions were met for the following 4 of 4 instruments used to perform Chemistry/Toxicology testing from 09/17/2024 to 08/11/2026: - Agilent 6890N Network Gas Chromatograph (ambient operating humidity: 5 to 95 percent (%)) - Agilent 5973 Network Mass Selective Detectors (Operating: 25% to 50% RH) - SCIEX Triple Quad 4500 LC-MS /MS (20% to 80%, non-condensing) -Olympus AU640 chemistry analyzer (40 to 80% RH, with no condensation) 2. The laboratory performed 9,760 Chemistry/Toxicology tests in 2025 (CMS 116, estimated annual volume, dated 8/11/2026). 3. The LD confirmed the findings above on 08/11/2026 at 1:30 pm.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) (b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and This STANDARD is not met as evidenced by: Based on review of competency assessment (CA) records and interview with the Laboratory Director (LD), the Technical Supervisor (TS) failed to assess the competency for 3 of 4 testing personnel (TP) through testing previously analyzed specimens, internal blind testing, or external proficiency testing samples for Chemistry /Toxicology examinations performed from 09/17/2024 to 08/11/2026. Findings include: 1. On the day of survey, 08/11/2026 at 12:30 pm, review of laboratory CA records revealed the TS did not include the assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples for 3 of 4 TP (CMS 209 personnel #1, 2 and 3, dated 8/11/2026) that performed Chemistry/Toxicology examinations from 09/17/2024 to 08/11/2026. 2. The LD confirmed the finding above on 08/11/2026 around 01:00 pm.
D6126	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi) (b)(8)(vi) Assessment of problem-solving skills; and This STANDARD is not met as evidenced by: Based on review of competency assessment (CA) records and interview with the Laboratory Director (LD), the Technical Supervisor (TS) failed to include the assessment of problem-solving skills in the competency evaluations assessed for 3 of 4 Testing Personnel (TP) that performed Chemistry/Toxicology examinations from 09 /17/2024 to 08/11/2026. Findings include: 1. On the day of survey, 08/11/2026 at 12: 30 pm, review of laboratory CA records revealed the TS did not include the

assessment of problem-solving skills in the CA for 3 of 4 TP (CMS 209 personnel #1, 2 and 3, dated 08/11/2026) that performed Chemistry/Toxicology examinations from 09/17/2024 to 08/11/2026. 2. The LD confirmed the finding above on 08/11/2026 around 01:00 pm.