

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2177163	(X3) Date Survey Completed 11/17/2025
Name of Provider or Supplier Highlands Hospital Toxicology Laboratory	Street Address, City, State 700 Park Street, Lower Level, Connellsville, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Laboratory's Quality Assessment (QA) Plan policy, QA documents, and interview with General Supervisor (GS) #1, the laboratory failed to follow established written policies to ensure the laboratory's QA Plan was maintained to monitor, assess, and correct problems identified in the general laboratory systems (493.1231 through 493.1236) for 2 of 2 years from 3/5/2024 to 11/17/2025. Findings include: 1. The laboratory's Quality Assessment Plan policy stated, "The QA plan will be implemented by review of the following monitors at the frequency and method of review specified. Proficiency Testing: PT surveys including Alt PT, CAP surveys or any other PT provider. Frequency-Biannual. Annual Calendar of QA Reviews: Review the monitor(s) assigned for each month. Document the review on the appropriate form and attach all supporting data and information. Biannually: complete the Proficiency checklists." 2. On the day of the survey, 11/17/2025 at 12:30 pm, the laboratory failed to provide documentation of the biannual QA assessment review performed for all PT surveys performed for 2 of 2 years from 3/5/2024 to 11/17/2025. 3. GS #1 confirmed the above findings on 11/17/2025 at 12:45 pm.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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,</p>

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 observation in the laboratory, review of laboratory temperature records, and interview with General Supervisor (GS) #1, the laboratory failed to monitor temperatures to ensure acceptable reagent storage temperatures were maintained on weekends and holidays for 425 of 623 days from 3/5/2024 to 11/17/2025. Findings include: 1. On the day of survey, 11/17/2025, at 2:30 pm, during the tour of the laboratory, the surveyor observed the following reagents stored in the laboratory: - Supelco Isopropanol. Storage requirements 2C to 30C. - Carolina Wash Concentrate. Storage requirements 8C to 30C. - Fast Detergent 1. Storage requirements 8C to 30C. - Fast Detergent 2. Storage requirements 8C to 30C. - Agilent ESI Low Conc Tuning Mix. Storage requirements 2C to 8C. - Rapid Hydrolysis Buffer. Storage requirements 2C to 8C. - IMCSzyme. Storage requirements 2C to 8C. 2. Review of the laboratory's temperature records revealed the laboratory failed to monitor and document temperatures to ensure acceptable reagent storage temperatures were maintained for 425 of 623 days from 3/5/2024 to 11/17/2025 when the laboratory was closed. 3. The laboratory performed 784,905 toxicology examinations in 2024 (CMS 116, estimated volume, dated 10/27/2025). 4. GS #1 confirmed the findings above on 11/17/2025 at 2:45 pm.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory and interview with the Lighthouse Consultant (LC), the laboratory failed to label 3 of 3 aliquoted reagents (methanol, isopropanol, and water) with the pertinent information required for proper use from 3/5/2024 to 11/17/2025. Findings include: 1. On the day of survey, 11/17/2025 at 2:30 pm, during the laboratory tour, observation of the laboratory revealed 3 of 3 containers used to aliquot reagents were not properly labeled with the following when toxicology examinations were performed from 3/4/2024 to 11/17/2025: - Storage requirements - Preparation and expiration dates 2. The laboratory performed 784,905 toxicology examinations in 2024 (CMS 116, estimated volume, dated 10/27/2025). 3. The LC confirmed the findings above on 11/17/2025 at 2:45 pm.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation, and interview with the Lighthouse Consultant (LC), the laboratory failed to ensure written procedures were followed to monitor, assess, and correct problems in the analytic systems (493.1251 through 493.1283) when biannual result comparisons performed for 2 of 2 Chem Agilent 6400 analyzers failed to meet the laboratory's established acceptable criteria from 3/4/2024 to 11/17/2025. Findings include: 1. The laboratory's Instrument/Method Comparison policy stated: "5.1.3: Review the data for each instrument and analyte to determine if the correlation is acceptable. For quantitative testing, the results are acceptable when the deviation does not exceed 20% for each positive analyte tested/compared. 5.2: Lab Director or designee: Review/Corrective Action/Documentation: Semi-annually review the instrument/method comparison data. If the results are not acceptable per the established criteria, assess any data and/or quality controls from test methods to determine if the data is valid." 2. On the day of survey, 11/17/2025 at 3:00 pm , review of the laboratory's Instrument comparison records revealed the laboratory failed to provide documentation for the assessment of any data/quality controls from the test methods used to determine the data validity when semi-annual instrument /method comparisons performed on 2 of 2 Chem Agilent 6400 analyzers failed to meet the laboratory's established acceptable criteria (>20% deviation in concentration) from 3/4/2024 to 11/17/2025. 3. The LC confirmed the above findings on 11/17/2025 at 3:15 pm.