Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2177163	06/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Highlands Hospital Toxicology Laboratory	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
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of comparison study records and interview with Laboratory Consultant (LC), the laboratory failed to have a system that evaluates twice a year the relationship between test results for 2 of 2 Liquid Chromatography Mass Spectrometry (LCMS) from 04/08/2021 to 04/14/2022. Findings include: 1. On the day of survey 06/09/2022 at 11:00 am, record review revealed, the laboratory only performed comparison studies for LCMS analyzer once a year from 04/08/2021 to 04 /14/2022. 2. This finding was confirmed by interview with Laboratory Consultant on 06/09/2022 at 11:30 am.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

	This STANDARD is not met as evidenced by: Based on review of the final patient test result and interview with the Laboratory Consultant (LC), the final patient test report failed to have the correct address of the laboratory where the toxicology test was performed from 06/18/2020 to 06/09/2022. Findings include: 1. On the day of survey 06/09/2022 at 10:54am, review of the final patient report revealed that the address on the final resulting report was not correct. 2. The address on the final report was 401 E. Murphy Avenue, Connellsville, Pa 15425 3. The LC confirmed the findings above on 06/09/2022 at 11:45am.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of competency assessment records and interview with the Laboratory Consultant (LC), the technical supervisor (TS) failed to perform direct observation of routine patient testing, specimen handling and processing for 1 of 1 testing personnel (TP) from 06/18/2020 to the day of survey. Findings Include: 1. On the day of survey 06/09/2022 at 11:00 a.m., review of 1 of 1 TP competency assessment records for toxicology indicated "direct observation through FaceTime on 12/29/2020 and 03/18 /2021". 2. Interview with the LC revealed that the TS has not been on site to perform direct observations for the competency assessment. 3. The LC confirmed the findings above on 06/09/2022 around 11:15 a.m. * Please note: Virtual observations are unacceptable.
D6124	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on review of competency assessment records and interview with the Laboratory Consultant (LC), the technical supervisor (TS) failed to perform direct observation of performance of instrument maintenance and function checks.for 1 of 1 testing personnel (TP) from 06/18/2020 to the day of survey. Findings Include: 1. On the day of survey 06/09/2022 at 11:00 a.m., review of 1 of 1 TP competency assessment records for toxicology indicated "direct observation through FaceTime on 12/29/2020 and 03/18/2021". 2. Interview with the LC revealed that the TS has not been on site to perform direct observations for the competency assessment form. 3. The LC confirmed the findings above on 06/09/2022 around 11:15 a.m. * Please note: Virtual observations are unacceptable.