Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2315997	06/25/2026
Name of Provider or Supplier	**Street Address, City, State**	
Huntsman Mental Health Institute	1000 W 3300 S, South Salt Lake, UT	

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 record review and interview, the laboratory failed to ensure that competency assessments were performed for 2 of 2 technical consultants (TC #1 and TC #2) for their duties as technical consultants. . Findings Include: 1. Review of the laboratory's personnel records revealed a lack of documented competency assessments for 2 of 2 technical consultants. 2. During an interview at approximately 2:56 PM, TC #1 confirmed that competency assessments had not been performed or documented for either TC #1 or TC #2 regarding their duties as technical consultants. .
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

	This STANDARD is not met as evidenced by: . Based on record review and interview with a technical consultant (TC) #1, the laboratory failed to perform control procedures at least once each day patient specimens were assayed or examined for 1 of 1 nonwaived test systems (iSTAT CHEM 8+). The laboratory routinely performed quality control testing only once per week and failed to establish an Individualized Quality Control Plan (IQCP) to support a reduced quality control frequency. . Findings Include: 1. Record review failed to locate an approved or established Individualized Quality Control Plan (IQCP)-including a Risk Assessment, Quality Control Plan, and Quality Assessment plan-for the iSTAT CHEM 8+ test system. 2. Review of the laboratory's quality control logs on 06/25/2026 revealed that control materials for the quantitative iSTAT CHEM 8+ test system were being analyzed and documented only once per week. 3. During an interview at approximately 3:40 PM, TC #1 confirmed that an IQCP had never been developed or implemented for the iSTAT CHEM 8+ test system to authorize a weekly quality control testing schedule. 4. The laboratory performed approximately 5500 iSTAT CHEM 8+ tests annually.