

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2183984	(X3) Date Survey Completed 01/26/2022
Name of Provider or Supplier High Throughput Testing Core (Httc)	Street Address, City, State University Of Texas Neural And Molecular Science, Austin, TX	
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	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493. 1447 Condition: Laboratories Performing High Complexity Testing; Technical Supervisor 493. 1459 Condition: Laboratories Performing High Complexity Testing; General Supervisor 493. 1487 Condition: Laboratories Performing High Complexity Testing; Testing Personnel
D6108	<p>LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447</p> <p>The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the CMS-209 Laboratory Personnel Report, laboratory personnel records and interview of facility personnel, the laboratory failed to ensure the individual designated as the Technical supervisor met the minimum qualifications for the high complexity tests performed in Virology. (refer to D6109)</p>
D6109	<p>TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449</p> <p>The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.</p>

	<p>This STANDARD is not met as evidenced by: Based upon review of the CMS Report 209 Laboratory Personnel Report, laboratory personnel records and interview of facility personnel, the laboratory failed to ensure the individual designated as the Technical Supervisor met the minimum education requirements for high complexity testing in Virology. The findings included: 1. Review of the CMS Report 209 Laboratory Personnel Report found the laboratory designated one individual as the Technical Supervisor. 2. Review of laboratory personnel records for the Technical Supervisor found no evaluation of credentials for degrees awarded outside the United States. The Technical Supervisor offered degrees from France as evidence of education. 3. Interview of the Technical Supervisor conducted January 25, 2022 at 10:44 AM confirmed she did not have an evaluation of her degree to ensure it met the minimum education requirements.</p>
<p>D6141</p>	<p>GENERAL SUPERVISOR CFR(s): 493.1459</p> <p>The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the CMS-209 Laboratory Personnel Report, laboratory personnel records and interview of facility personnel, the laboratory failed to ensure the individual designated as the General supervisor met the minimum qualifications for the high complexity tests performed in Virology. (refer to D6142)</p>
<p>D6142</p>	<p>GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461</p> <p>The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.</p> <p>This STANDARD is not met as evidenced by: Based upon review of the CMS Report 209 Laboratory Personnel Report, laboratory personnel records and interview of facility personnel, the laboratory failed to ensure the individual designated as the General Supervisor met the minimum education requirements for high complexity testing in Virology. The findings included: 1. Review of the CMS Report 209 Laboratory Personnel Report found the laboratory designated one individual as the General Supervisor. 2. Review of laboratory personnel records for the General Supervisor found no evaluation of credentials for degrees awarded outside the United States. The Technical Supervisor offered degrees from France as evidence of education. 3. Interview of the Technical Supervisor conducted January 25, 2022 at 10:44 AM confirmed she did not have an evaluation of her degree to ensure it met the minimum education requirements.</p>
<p>D6168</p>	<p>TESTING PERSONNEL</p>

CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:

Based on a review of the CMS-209 Laboratory Personnel Report, laboratory personnel records and interview of facility personnel, the laboratory failed to ensure one of three testing personnel met the minimum education qualifications for the high complexity tests performed in Virology. (refer to D6170)

D6170

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(a)

Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:

Based upon review of the CMS Report 209 Laboratory Personnel Report, laboratory personnel records and interview of facility personnel, the laboratory failed to ensure one of three testing personnel met the minimum education requirements for high complexity testing in Virology. The findings included: 1. Review of the CMS Report 209 Laboratory Personnel Report found the laboratory designated three testing personnel performing high complexity testing. 2. Review of laboratory personnel records for Testing Person three found no evaluation of credentials for degrees awarded outside the United States. The Technical Supervisor offered degrees from France as evidence of education. 3. Interview of the Technical Supervisor conducted January 25, 2022 at 10:44 AM confirmed she did not have an evaluation of her degree to ensure it met the minimum education requirements.