

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2086349	(X3) Date Survey Completed 09/08/2021
Name of Provider or Supplier Novus Adult Care Services	Street Address, City, State 1565 Linden Street, Bethlehem, 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	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedures and interview with the operations and general managers, the laboratory failed to follow their competency assessment (CA) procedure to assess the competency for 7 of 8 testing personnel (TP) performing rapid HIV and syphilis testing and for 2 of 3 TP analyzing potassium hydroxide (KOH) microscopic examinations in 2021. Findings include: 1. The Competency policy states, "each employee will have competency assessed and documented for each procedure the employee performs. This is done at initial training, six months after initial employment and annually thereafter." 2. On the day of survey, 09/08/2021, the laboratory could not provide initial training and 6 month competency for 7 of 8 TP performing rapid HIV and syphilis testing of 2 of 3 TP analyzing KOH microscopic examinations in 2021. 3. The operations and general managers confirmed the findings above on 09/08/2021 around 12:15 pm.</p>
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the operations and general</p>

	<p>managers, the laboratory failed to provide a written or electronic request for the HIV and Syphilis combo kit testing ordered from an authorized person in 2021. Finding Include: 1. On the day of survey, 09/08/2021, review of patient records revealed, the laboratory did not have a written or electronic requests for HIV and Syphilis combo kit testing ordered from an authorized person in 2021. 2. The operations and general managers confirmed the findings above on 09/08/2021 around 12:00 pm.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedures and interview with the operations and general managers, the laboratory failed to establish a policy for The Chembio Diagnostics Systems DPP HIV-Syphilis Rapid Test kit in 2021. Findings include: 1. On the day of survey, 09/08/2021, the laboratory could not provide a policy for the Chembio Diagnostics Systems DPP HIV-Syphilis Rapid Test kits performed in the laboratory. 2. The operations and general managers confirmed the finding above on 09/08/2021 around 12:45 pm.</p>
<p>D5449</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with the operations and general managers, the laboratory failed to perform QC each day of patient testing for the Chembio Diagnostics Systems DPP HIV-Syphilis Rapid Test kits and for potassium hydroxide (KOH) microscopic examinations performed in 2021. Findings Include: 1. On the day of survey, 09/08/2021, review of QC records revealed the laboratory did not document QC performed each day of patient testing for the Chembio Diagnostics Systems DPP HIV-Syphilis Rapid Test kits and for KOH microscopic examinations performed in 2021. 2. The operations and general managers confirmed on 09/08/2021 around 1:30 pm, that QC was not documented each day of patient testing.</p>
<p>D6056</p>	<p>CLINICAL CONSULTANT CFR(s): 493.1415</p> <p>The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part.</p>

This CONDITION is not met as evidenced by:
Based on review of records and interview with the operations and general managers, 1 of 1 clinical consultant (CC) failed to meet the qualification requirements of 493.1417. Findings Include: Refer to D6057.

D6057

CLINICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1417

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.

This STANDARD is not met as evidenced by:
Based on review of records and interview with the operations and general managers, 1 of 1 clinical consultant (CC) failed to meet the qualification requirements of 493.1417. Findings Include: 1. On the day of survey, 09/08/2021, the laboratory could not provide educational credentials to qualify 1 of 1 CC. 2. The laboratory was given a 09/15/2021 to provide educational credentials that qualifies as 1 of 1 CC under the requirements of 493.1417. 3. On 09/15/2021, the general manager provide the following documents for the CC: University: LaSalle University. Degree: Master of Sciences in Nursing. Major: Adult Nurse Practitioner. 4. On 09/16/2021, review of the CC educational credentials revealed, the CC does not meet the qualification requirements of 493.1417.