

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D0353308	<b>(X3) Date Survey Completed</b>  06/16/2025
<b>Name of Provider or Supplier</b>  Healthnet Community Health Centers	<b>Street Address, City, State</b>  3403 E Raymond Street, Indianapolis, IN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A proficiency testing referral complaint desk review survey was completed on 6/16 /2025. The following condition-level deficiencies were found to be out of compliance: D2000- 42 C.F.R. 493.801 Condition: Enrollment and Testing of Samples D6000- 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director D6033- 42 C.F.R. 493.1409 Condition: Technical Consultant Moderate Complexity Testing
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of documentation submitted from the laboratory and interview with the laboratory director and technical consultant (SP1), the laboratory failed to test proficiency samples in the same manner as patient testing. The laboratory sent Proficiency Testing (PT) Samples from the Wisconsin State Laboratory of Hygiene Proficiency Testing (WSLH PT) to laboratory (Lab) B and to testing personnel at other sites under Lab A's Clinical Laboratory Improvement Amendment (CLIA) number prior to the PT end date. The PT materials for one of one event (Event 1, 2025-MiscQA_POC1), were sent to other sites under Lab A's CLIA number prior to the PT event end date of April 18, 2025. Refer to D2012. The PT materials for one of one event (Event 1, 2025-MiscQA_POC1), were sent to Lab B (Clinical Laboratory</p>

Improvement Amendment (CLIA) number 15D2253868) prior to the PT event end date for Lab A (CLIA number 15D0353308). Refer to D2013.

**D2012**

**TESTING OF PROFICIENCY TESTING SAMPLES**

(b)(4) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:

Based on review of documentation submitted from the laboratory and interview with the laboratory director and technical consultant (SP1), the laboratory sent Proficiency Testing (PT) Samples from the Wisconsin State Laboratory of Hygiene Proficiency Testing (WSLH PT) to sites under Lab A's CLIA number for personnel competency prior to the PT event end date. The PT materials for one of one event (Event 1, 2025-MiscQA\_POC1), were sent to other sites under Lab A's CLIA number prior to the PT event end date of April 18, 2025. Findings included: 1. In an interview on 6/2/25 at 3: 30 pm, SP1 (Laboratory Director) explained they were the laboratory director for Lab A and they did not realize that they could not share PT materials with the other locations under the CLIA number for Lab A prior to the survey event expiration date. 2. In an interview on 6/3/25 at 2:30, SP1 (Laboratory Director) confirmed that they did choose one employee from Lab A to perform testing for PT event 1 2025 "PT 2025-MiscQA\_POC1" and then brought Lab B before the end of the survey submission date. SP1 further confirmed that PT event 1 2025 "PT 2025-MiscQA\_POC1 was performed by all testing personnel for competency at Lab A sites. 3. Review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification CMS FORM 116, signed by SP1 on 6/12/2025, confirmed Lab A has 17 locations under the CLIA number that perform waived testing, potassium hydroxide (KOH), wet mount preparation (wet mount), and fern testing. 4. Total testing volume: 13,900

**D2013**

**TESTING OF PROFICIENCY TESTING SAMPLES**

CFR(s): 493.801(b)(4)

(b)(5) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for

testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:

Based on review of documentation submitted from the laboratory and interview with the laboratory director and technical consultant (SP1), the laboratory sent Proficiency Testing (PT) Samples from the Wisconsin State Laboratory of Hygiene Proficiency Testing (WSLH PT) to Laboratory (Lab) B for personnel competency prior to the end date of the PT event. The PT survey samples for one of one event (Event 1, 2025-MiscQA\_POC1), were sent to Lab B (CLIA number 15D2253868) prior to the PT event end date for Lab A (CLIA number 15D0353308) on April 18, 2025. Findings include: 1) The proficiency testing policy titled: Proficiency Testing, Procedure Number: L14, reviewed by SP1 (Laboratory Director) on 3/5/25, under I. Description of Specimen Testing required, "7. Once the event date has expired and results are sent to the vendor, then the other lab associates will compete the testing to meet their competency testing requirements ... (9) Testing staff is (Sic) prohibited from sending proficiency testing specimens to other labs for testing." 2) In an interview on 6/2/25 at 3:30 pm, SP1 (Laboratory Director), explained that they were hired as Laboratory Director in September of 2024, for both Lab A and Lab B. Lab A and Lab B both have multiple sites under their CLIA numbers. SP1 confirmed that Lab B was not enrolled in PT when wet mount preparation (wet mount) and potassium hydroxide (KOH) testing started in 2022. Lab B was not enrolled in PT for events 1 and 2 in 2023, 2024 or for event 1 of 2025. SP1 further explained they did not realize that they could not share PT materials with the other locations under the CLIA number for Lab A nor their other CLIA laboratory (Lab B) for testing prior to the survey event expiration date. 3) In an interview on 6/3/25 at 2:30, SP1 (Laboratory Director) confirmed that they did choose one employee from Lab A to perform testing for PT event 1 2025 "PT 2025-MiscQA\_POC1" and then brought it to Lab B before the end of the survey submission date. SP1 confirmed that testing on four of four samples for PT event 1 2025 "PT 2025-MiscQA\_POC1 was performed by all testing personnel for competency at both Lab A and Lab B. 4) Proficiency documentation for event 1 2025 indicated the following: a) The PT event "WSLH PT 2025-MiscQA\_POC1 2507520" from Wisconsin State Laboratory of Hygiene Proficiency Testing (WSLH PT) was for Lab A (CLIA ID: 15D0353308). b) The attestation was signed by SP1 (Laboratory Director) on 4/16/25. c) Results were submitted on 4/16/2025 at 9:16 am for Module 3170. d) The due date was April 18, 2025. 5) Review of Personnel Files indicated WSLH Proficiency Testing 2025A performed by Lab B staff: a) Lab B SP7 no date of completion. b) Lav B SP8 no date of completion. 4) Total testing volume: 13, 900

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of documentation submitted from the laboratory and interviews with the laboratory director and technical consultant (SP1), the laboratory director failed to ensure proficiency samples were tested as required. The laboratory sent Proficiency Testing (PT) Samples from the Wisconsin State Laboratory of Hygiene Proficiency

	<p>Testing (WSLH PT) to laboratory (Lab) B and to testing personnel at other sites under Lab A's Clinical Laboratory Improvement Amendment (CLIA) number prior to the PT end date. The PT materials for one of one event (Event 1, 2025-MiscQA_POC1), were sent to other sites under Lab A's CLIA number prior to the PT event end date of April 18, 2025. Refer to D6016. The PT materials for one of one event (Event 1, 2025-MiscQA_POC1), were sent to Lab B (Clinical Laboratory Improvement Amendment (CLIA) number 15D2253868) prior to the PT event end date for Lab A (CLIA number 15D0353308). Refer to D6016</p>
<p><b>D6016</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1407(e)(4)(i)</p> <p>(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by:  Based on review of proficiency testing documentation and interviews with the laboratory director and technical consultant (SP1), the laboratory director failed to ensure proficiency samples were tested as required under Subpart H. The laboratory sent Proficiency Testing (PT) Samples from the Wisconsin State Laboratory of Hygiene Proficiency Testing (WSLH PT) to laboratory (Lab) B and to testing personnel at other sites under Lab A's Clinical Laboratory Improvement Amendment (CLIA) number prior to the PT end date. The PT materials for one of one event (Event 1, 2025-MiscQA_POC1), were sent to other sites under Lab A's CLIA number prior to the PT event end date of April 18, 2025. Refer to D2012. The PT materials for one of one event (Event 1, 2025-MiscQA_POC1), were sent to Lab B (Clinical Laboratory Improvement Amendment (CLIA) number 15D2253868) prior to the PT event end date for Lab A (CLIA number 15D0353308). Refer to D2013.</p>
<p><b>D6033</b></p>	<p><b>TECHNICAL CONSULTANT-MODERATE COMPLEXITY</b>  CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by:  Based on record review and interview, the laboratory failed to ensure one of one (SP-1) personnel performing the duties of a technical consultant (TC) was qualified from September 2024 to the date of the survey. Refer to D6035.</p>
<p><b>D6035</b></p>	<p><b>TECHNICAL CONSULTANT QUALIFICATIONS</b>  CFR(s): 493.1411</p> <p>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of</p>

podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to ensure one of one (SP-1) personnel performing the duties of a technical consultant (TC) was qualified from September 2024 to the date of the survey. Findings included: 1. In an interview on 6/2/2025 at 1 pm, SP-1 (Laboratory director) indicated they started in their position of laboratory director and technical consultant for Lab A and Lab B in September 2024. 2. In an interview on 6/3/2025 at 1 pm, SP1 (Laboratory Director) indicated they were trained for wet mount and KOH testing after being hired for their position at Lab A and Lab B. SP1 confirmed that there was not any record made of their training because no one was qualified to formally check them off. 3. Review of "Laboratory Personnel Report (CLIA)", signed by the laboratory director (SP-1) on 6/12/2025, indicated SP-1 was the laboratory director and technical consultant for the subspecialties of mycology and parasitology. 4. Review of personnel documents for SP-1 indicated SP-1 had a bachelor's degree in biology and 16 months of non-waived training and experience, but the laboratory experience did not include the specialty of microbiology or the subspecialties of mycology or parasitology. 5. In interview on 6/16/25 at 1:15 pm, SP-1 confirmed they did not have experience in the subspecialties of mycology and parasitology. 6. Annual test volume 13,900