

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0410656	(X3) Date Survey Completed 06/03/2025
Name of Provider or Supplier Bridgercare	Street Address, City, State 1288 North 14th Ave, Suite 201, Bozeman, MT	
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a review of verification records, laboratory procedures, and an interview with the laboratory director (LD) #1, the laboratory failed to verify the performance specifications comparable to those established by the manufacturer for accuracy and precision of the Xpert Trichomonas Vaginalis (TV) test performed on the GeneXpert Instrument before reporting patient test results from February 27, 2025, to June 03, 2025. Findings: 1. The laboratory failed to provide studies to verify the performance specifications comparable to those established by the manufacturer for accuracy and precision for the Xpert TV test performed on the GeneXpert Instrument from February 27, 2025, to June 03, 2025. 2. Based on the microbiology annual test volume, 3500 TV patient tests were performed in the last 12 months. 3. An interview with LD #1 on June 03, 2025, at 11:00 AM confirmed the lack of accuracy and precision verification studies for the Xpert TV cartridge performed on the GeneXpert before reporting patient test results from February 27, 2025, to June 03, 2025.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>(d) Unless CMS Approves a procedure, specified in Appendix C of the State</p>

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 a review of quality control (QC) records, procedures, and interviews with laboratory director (LD) #1, the laboratory failed to establish an Individualized Quality Control Plan (IQCP) for the Xpert Trichomonas vaginalis (TV) test performed on the GeneXpert Instrument from February 27, 2025, to June 03, 2025. Findings: 1. A review of the TV Control log revealed that the laboratory was performing positive and negative control for each new lot and shipment of Xpert TV test. 2. There was no IQCP evaluation containing a risk assessment, a quality control plan, and a quality assessment plan to support the QC practices that are less stringent than the regulatory quality control requirement of performing positive and negative QC each day of patient testing. 3. Based on the microbiology annual test volume, 3500 TV patient tests were performed in the last 12 months. 4. An interview with LD #1 on June 3, 2025, at 11:15 AM confirmed that the laboratory failed to establish an IQCP for alternative QC practices for the Xpert Trichomonas vaginalis (TV) test performed on the GeneXpert Instrument from February 27, 2025, to June 03, 2025.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a record review of testing personnel files, the CMS-209 Laboratory Personnel Report, procedure, and an interview with the laboratory director (LD) #1, the technical consultant failed to follow their procedure to evaluate and document competency assessment for four of six testing personnel (TP) at least semiannual in the first year of performing moderate complexity testing on the GeneXpert from June 3, 2023, to June 3, 2025. Findings: 1. A review of the testing personnel's "Competency Checklist for Testing Personnel" lacked evaluation of the six-month competency assessment for four of six testing personnel (TP-1, TP-2, TP-3, TP-4) listed on the CMS 209 form from June 3, 2023, to June 3, 2025. 2. A review of "Personnel Training and Competency Management" procedures revealed the technical consultant failed to follow their procedure to assess competency "semi-annually during the first year of employment and annually thereafter" for testing personnel performing Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis assays on the GeneXpert. 3. An interview with TC #1 on June 03, 2025, at 8:40 AM, confirmed the technical consultant failed to follow their procedure to evaluate and document competency assessment for four of six testing personnel (TP) at least semiannual in the first year of performing moderate complexity testing on the GeneXpert from June 3, 2023, to June 3, 2025.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:

Based on a record review of testing personnel files, the CMS-209 Laboratory Personnel Report, procedure, and an interview with the laboratory director (LD) #1, the technical consultant (TC) #1 failed to follow their procedure to perform an annual competency assessment for three of six testing personnel (TP) for the year 2024. Findings: 1. A review of the testing personnel's "Competency Checklist for Testing Personnel" form lacked evaluation of the annual competency assessment for three of six testing personnel (TP-1, TP-2, and TP-4) listed on the CMS 209 form for the year 2024. 2. A review of the "Personnel Training and Competency Management" procedure revealed the TC failed to follow their procedure to perform competency assessments "semi-annually during the first year of employment and annually thereafter" for testing personnel performing Chlamydia trachomatis, Neisseria gonorrhoeae and Trichomonas vaginalis assays performed on the GeneXpert. 3. An interview with LD #1 on June 03, 2025, at 8:45 AM, confirmed the technical consultant failed to follow their procedure to perform an annual competency assessment for three of six testing personnel for the year 2024.

D6064

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(a)

Each individual performing moderate complexity testing must-- (a) possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

This STANDARD is not met as evidenced by:

Based on a review of testing personnel's qualifications, training, and competencies records and an interview with the laboratory director (LD) #1, the laboratory failed to provide a Montana state license for five of six testing personnel (TP) approved to perform non-waived testing from June 3, 2023 to June 3, 2025. Findings: 1. A review of the CMS-209 form (Laboratory Personnel Report (CLIA)) filled out by the laboratory director revealed five of six testing personnel (TP-2, TP-3, TP-4, TP-5, and TP-6) lacked a Montana State license to perform non-waived diagnostic testing. Administrative Rules Title 24, chapter 129, subchapter 6, ARM Licensing. 37-34-301. License required. 2. A review of personnel's "Competency Checklist for Testing Personnel" revealed that the laboratory director had approved testing personnel (TP-2, TP-3, TP-4, TP-5, and TP-6) to perform non-waived testing. 3. An interview with LD #1 on June 3, 2025, at 11:30 a.m. confirmed that five of six testing personnel lacked the Montana State License required to perform non-waived diagnostic testing from June 3, 2023, to June 3, 2025.