

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  06D0519595	<b>(X3) Date Survey Completed</b>  10/14/2024
<b>Name of Provider or Supplier</b>  Pioneers Medical Center	<b>Street Address, City, State</b>  100 Pioneers Medical Center Drive, Meeker, CO	
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>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on an onsite review of the laboratory's proficiency testing performance and an interview with the laboratory's general supervisor, the laboratory failed to achieve satisfactory performance scores for compatibility testing for two consecutive events, Event 3 in 2023 and Event 1 in 2024. See D2181.</p>
<b>D2181</b>	<p><b>COMPATIBILITY TESTING</b> CFR(s): 493.863(e)</p> <p>Failure to achieve an overall testing event score of satisfactory for two consecutive</p>

testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's proficiency testing scores report from the American Proficiency Institute (API) and an interview with the laboratory's general supervisor (GS), the laboratory failed to achieve a score of 100% for compatibility testing for Event 3 in 2023, and Event 1 in 2024. Findings include: 1. A review of the laboratory's PT records on October 14, 2024, at approximately 11:00 AM, revealed the proficiency testing scores for compatibility testing was 80% for 2023 Event 3, and was 60% for Event 1 in 2024. 2. An interview with laboratory manager on October 14, 2024, at 11:05 AM, confirmed two consecutive unsuccessful proficiency scores for compatibility testing for event 3 in 2023, and event 1 in 2024.

**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 review of the laboratory's personnel files, policies and procedures manual, and an interview with the laboratory's general supervisor (GS), the laboratory failed to assess the competency of testing personnel (TP) after their initial competency but within their first 6 months of employment; assess or establish a written policy or procedure for assessing the competency of personnel in the position of technical supervisor (TS), and GS since the last recertification survey was conducted on January 28, 2022. The laboratory conducts approximately 78,825 tests annually. Findings include: 1. A review of the laboratory's personnel files revealed the laboratory was assessing initial and annual competency for TP, but not assessing competency at least 6 months after initial competency was assessed in TP first year of employment. 2. A review of the laboratory's personnel files, and policies and procedures manual revealed that the laboratory failed to assess the competency of, or establish a written policy or procedure for assessing the competency for one out of one TS, and one out of one GS listed on the CMS-209 Form. 3. Based on an interview with the GS, on October 14, 2024, at approximately 3:00 PM, confirmed that the laboratory failed to assess the competency of TP within 6 months after completing their initial competencies, and failed to assess the competency of, or establish a written policy or procedure to assess the competency of personnel in the positions of TS, and GS.

**D5445**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(1)(2)(g)

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. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's individualized quality control plan (IQCP), quality control (QC) records, and an interview with the laboratory's general supervisor (GS), the laboratory failed to follow its IQCP for testing external controls on its Cepheid analyzer testing platform for the Xpert Xpress SARS-CoV-2/Flu/RSV Plus, Xpert MRSA NxG, and Xpert CT/NG assays since the last recertification survey was performed on January 28, 2022. Findings include: 1. Based on a review of the laboratory's IQCP QC frequency requirements, the laboratory requires positive and negative QC to be performed when the laboratory first opens a new lot or new shipment of the same lot of reagents, or every 30 days if a new shipment, or new lot of reagents is not received or opened by the laboratory for the Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV Plus, Xpert MRSA NxG, and Xpert CT/NG assays. 2. Based on a review of the laboratory's QC records, the laboratory failed to follow its IQCP QC frequency by not performing QC every 30 days as required if a new shipment has not been opened, or a new lot number has not been put into use for the Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV Plus, Xpert MRSA NxG, and Xpert CT/NG assays. 3. An interview with the laboratory's GS, on October 14, 2024, at approximately 1:45 PM, confirmed that the laboratory was not following its IQCP QC requirements for the Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV Plus, Xpert MRSA NxG, and Xpert CT/NG assays by failing to perform QC every 30 days if a new shipment had not been received by the laboratory, or a new lot number had not been put into use. 4. The laboratory performs approximately 702 Xpert Xpress SARS-CoV-2/Flu/RSV Plus, 183 Xpert MRSA NxG, and 75 Xpert CT/NG assays on the Cepheid analyzer annually.

**D5775**

**COMPARISON OF TEST RESULTS**

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on a records review, a review of the laboratory's policies and procedures manual, and an interview with the laboratory's general supervisor (GS), the laboratory failed to compare, or establish a policy or procedure to compare their Sysmex XN-550 hematology analyzer to their Sysmex XS-1000 hematology analyzer, iStat CG8+ chemistry cartridge to their Vitros 5600 chemistry analyzer, iStat EG6 blood gas cartridge to their ABL 80 Flex blood gas analyzer, Biofire respiratory panel to their Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV panel, and automated white blood cell (WBC) differential to manual WBC differential at least semiannually since the laboratory's last recertification survey was performed on January 28, 2022. Findings include: 1. Based on a records review, the laboratory failed to compare their Sysmex XN-550 hematology analyzer to their Sysmex XS-1000 hematology analyzer, iStat CG8+ chemistry cartridge to their Vitros 5600 chemistry analyzer, iStat EG6 blood gas cartridge to their ABL 80 Flex blood gas analyzer, Biofire respiratory panel to

their Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV panel, and automated WBC differential to manual WBC differential at least semiannually. 2. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish a policy or procedure to compare their Sysmex XN-550 hematology analyzer to their Sysmex XS-1000 hematology analyzer, iStat CG8+ chemistry cartridge to their Vitros 5600 chemistry analyzer, iStat EG6 blood gas cartridge to their ABL 80 Flex blood gas analyzer, Biofire respiratory panel to their Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV panel, and automated WBC differential to manual WBC differential at least semiannually. 3. An interview with the laboratory's GS, on October 14, 2024 at approximately 2:30 PM, confirmed that the laboratory failed to compare, and establish a policy or procedure to compare their Sysmex XN-550 hematology analyzer to their Sysmex XS-1000 hematology analyzer, iStat CG8+ chemistry cartridge to their Vitros 5600 chemistry analyzer, iStat EG6 blood gas cartridge to their ABL 80 Flex blood gas analyzer, Biofire respiratory panel to their Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV panel, and automated WBC differential to manual WBC differential at least semiannually. 4. The laboratory performs approximately 21,849 hematology tests, 3,111 microbiology tests, and 53,706 chemistry tests annually.