Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 38D0628589	**(X3) Date Survey Completed** 10/26/2022
Name of Provider or Supplier Pioneer Memorial Hospital Lab	**Street Address, City, State** 564 E Pioneer Dr, Heppner, OR	
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**
D2004	ENROLLMENT CFR(s): 493.801(a)(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation; This STANDARD is not met as evidenced by: Based on review of the laboratory's Casper Report 0155D and phone conversation with the Technical Supervisor (TS) the laboratory switched proficiency testing providers from American Association of Bioanalyst (AAB) to the College of American Pathologist (CAP) in the middle of the calendar year. Findings include: 1. AAB 2nd event 2021 - Compatibility Testing - 80% 2. AAB 1st event 2022 - Compatibility Testing - 60% 3. CAP 2nd event 2022 - Compatibility Testing - 80% 4. The laboratory performs a total of sixty (60) compatibility testing per year. 5. The TS confirmed these findings during the phone conversation on 10/05/2022 @ 15:27.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on Proficiency Testing (PT) desk review of the American Association of Bioanalyst (AAB) and the College of American Pathologists (CAP) proficiency testing revealed the laboratory had unsuccessful participation for compatibility testing for three (3) out of four (4) consecutive testing events. Refer to D2173 and D2179.
D2173	COMPATIBILITY TESTING CFR(s): 493.863(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on Proficiency Testing (PT) desk review of the American Association of Bioanalysts (AAB) proficiency testing and the College of American Pathology (CAP) and phone conversation with the Technical Supervisor (TS) the laboratory had failed to attain an overall testing event score of 100% for three (3) out of four (4) consecutive events for Compatibility Testing in the specialty Immonohematology. Findings include: 1. AAB 2nd event 2021 - Compatibility Testing - 80% 2. AAB 1st event 2022 - Compatibility Testing - 60% 3. CAP 2nd event 2022 - Compatibility Testing - 80% 4. The laboratory performs a total of sixty (60) compatibility testing per year. 5. The TS confirmed these findings during the phone conversation on 10/05 /2022 @ 15:27.
D2179	COMPATIBILITY TESTING CFR(s): 493.863(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on Proficiency Testing (PT) desk review of the American Association of Bioanalysts (AAB) proficiency testing and the College of American Pathology (CAP) and phone conversation with the Technical Supervisor (TS) the laboratory had failed to employ technical assistance and to follow the standard operating procedures (SOP) for compatibility testing EOC #3 Gel SOP and antibody screening EOC #1 SOP procedures that resulted in Compatibility Testing failures in three (3) out of four (4) consecutive testing events in the specialty Immonohematology. Findings include: 1. AAB 2nd event 2021 - Compatibility Testing - 80% 2. AAB 1st event 2022 -

	Compatibility Testing - 60% 3. CAP 2nd event 2022 - Compatibility Testing - 80% 4. The laboratory performs a total of sixty (60) compatibility testing per year. 5. The TS confirmed these findings during the phone conversation on 10/05/2022 @ 15:27.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Proficiency Testing (PT) records the Laboratory Director (LD) did not fulfill his responsibilities to provide overall management and direction of the laboratory. Refer to D6091 and D6092.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on Proficiency Testing (PT) desk review of the American Association of Bioanalysts (AAB) proficiency testing and the College of American Pathology (CAP) and phone conversation with the Technical Supervisor (TS) , the Laboratory Director (LD) or his/her designee failed to review PT performance to make sure all PT testing were done correctly and accurately. Findings include. 1. AAB 2nd event 2021 - Compatibility Testing - 80% 2. AAB 1st event 2022 - Compatibility Testing - 60% 3. CAP 2nd event 2022 - Compatibility Testing - 80% 4. The laboratory performs a total of sixty (60) compatibility testing per year. 5. This was confirmed by the TS during our phone conversation on 10/05/2022 @ 16:21 PM.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) from the American Association of Bioanalyst (AAB) and the College of American Pathologist (CAP) and phone conversation with the Technical Supervisor (TS) the laboratory failed to institute the acceptable plan of corrective action that was written in the initial unsuccessful proficiency testing performance dated 07/27/2022. Finding include. 1. A PT desk review of graded PT results from AAB and CAP revealed the laboratory director failed to ensure that the laboratory maintained successful participation for the analyte compatibility testing for three (3) of three (4) proficiency events in 2021 and 2022. a) AAB 2nd event 2021 - Compatibility Testing - 80% b) AAB 1st event 2022 -

	Compatibility Testing - 60% c) CAP 2nd event 2022 - Compatibility Testing - 80% 2. A review of previous CMS-2567 for unsuccessful participation dated 07/27/2022 and the corresponding AoC/EoC dated 07/27/2022 identified that the laboratory director failed to ensure that the plan of corrective action was successful from the previous proficiency testing failures for the analyte compatibility testing. 3. The laboratory performs a total of sixty (60) compatibility testing per year. 4. This was confirmed by the TS during our phone conversation 10/05/2022 @ 16:21 PM.