Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0656873	12/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Corvallis Clinic, Pc Laboratory,The	3680 Nw Samaritan Dr, Asbury Bldg 2nd Floor, Corvallis, 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
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: Proficiency Testing (PT) desk review of the College of American Pathologists (CAP) proficiency testing showed the laboratory had unsucessful participation for three(3) of three (3) consecutive events in 2021 for the analyte total bilirubin. Refer to D2087.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte

	in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and phone conversation with the Technical Supervisor (TS) the laboratory had unsuccessful performance in three (3) of three (3) consecutive events in 2021 for the analyte total bilirubin. Finding include: 1. CAP 1st Event 2021 - total bilirubin = 0% 2. CAP 2nd Event 2021 - total bilirubin = 0% 3. CAP 3rd Event 2021 - total bilirubin = 0% 4. This was confirmed by the TS during our phone conversation 11/30/2021 @ 16:58 PM.
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 review of proficiency testing (PT) records from the College of American Pathologist (CAP) and phone conversation with the Technical Supervisor (TS) the laboratory director or his/ her designee failed to review proficiency testing performance to make sure all PT were resulted correctly. Findings include: 1. CAP 1st Event 2021 - total bilirubin = 0%. 2. CAP 2nd Event 2021 - total bilirubin = 0%. 3. CAP 3rd Event 2021 - total bilirubin = 0%. 4. This was confirmed by the TS during our phone conversation on 11/30/2021 @ 16:58.
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 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 08/09/2021. Findings include: 1.

	A PT desk review of graded PT results from CAP revealed the laboratory director failed to ensure that the laboratory maintained successful participation for the analyte total bilirubin for three (3) of three (3) consecutive proficiency events in 2021. a) CAP 1st Event of 2021 - total bilirubin = 0%. b) CAP 2nd Event of 2021 - total bilirubin = 0%. c) CAP 3rd Event 2021 - total bilirubin = 0%. 2. A review of previous CMS-2567 for unsuccessful participation dated 08/09/2021 and the corresponding AoC/EoC dated 08/13/2021 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 total bilirubin. 3. This was confirmed by the TS during our phone conversation 11/30/2021 @ 16:58.