

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D1081173	<b>(X3) Date Survey Completed</b>  03/29/2022
<b>Name of Provider or Supplier</b>  Pine Rest Christian Mental Health Services	<b>Street Address, City, State</b>  300 68th Street Se, Grand Rapids, MI	
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>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. A. Based on record review and interview with the Director of Quality (DQ), the laboratory failed to follow manufacturers' instructions for internal quality control performance for the Medline hCG Pregnancy Test Strip (Urine) and the One Step Multi-Drug Screen Test Cup (Urine) for 2 (March 2020 to March 2022) of 2 years of testing. Findings include: 1. A review of the manufacturer's instructions for the Medline hCG Pregnancy Test Strip (Urine) revealed a section titled "Quality Control" stating, "Internal procedural controls are included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique." 2. A review of the manufacturer's instructions for the One Step Multi-Drug Screen Test Cup (Urine) revealed a section titled "Quality Control" stating, "A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirm sufficient specimen volume, adequate membrane wicking and correct procedural technique." 3. A phone interview on 3/31/2022 at 4:21 pm with the DQ revealed the laboratory did not document the internal positive quality control for the testing listed above. B. Based on record review and interview with the Director of Quality (DQ), the laboratory failed to follow manufacturers' instructions for external quality control performance for the Medline hCG Pregnancy Test Strip (Urine) and the One Step Multi-Drug Screen Test Cup (Urine) for 2 (March 2020 to March 2022) of 2 years of testing. Findings include: 1. A review of the manufacturer's instructions for the Medline hCG Pregnancy Test Strip (Urine) revealed a section titled "Quality Control" stating, "A clear background is an</p>

internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test results." 2. A phone interview on 3/31/2022 at 4:21 pm with the DQ revealed the laboratory did not document the internal negative quality control for the testing listed above. C. Based on observation, lack of a timer, and interview with the Urgent Care Manager (UCM), the laboratory failed to provide a timer for the reading of the Medline hCG Pregnancy Test Strip (Urine) for 2 (March 2020 to March 2022) of 2 years of testing. Findings include: 1. During the tour of the Urgent Care on 3/29/2022 at approximately 12:30 pm, the surveyor observed in the patient restroom where the testing is performed there was no timer present. 2. A review of the manufacturer's instructions for the Medline hCG Pregnancy Test Strip (Urine) revealed a section titled "Direction for Use" stating "Place the test strip on a non-absorbent, flat surface, start the timer and wait for the red line(s) to appear." 3. When queried on 3/29/2022 at approximately 12:30 pm, the UCM stated the medical assistants use their watches. 4. A interview on 3/29/2022 at approximately 12:30 pm, the UCM confirmed there is no set timer for the medical assistants to use to perform the laboratory testing.