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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 32D2210988 | (X3) Date Survey Completed 01/20/2022 |
| Name of Provider or Supplier Laguna Healthcare Corporation | Street Address, City, State 6 Basswood Rd, Paraje, NM | |
| 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 |
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| D1001 | <p>CERTIFICATE OF WAIVER TESTS 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: Based on direct observation, review of manufacturers' instructions for the Afinion 2 and Piccolo Xpress analyzers, laboratory environmental records, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for waived testing performed on the Afinion 2 and Piccolo Xpress analyzers. Findings included: 1. A tour of the laboratory area on 01/20/2022 at 10:35 am revealed the following testing instruments: a. Afinion 2 Analyzer for testing Hemoglobin A1C (Serial Number 172.16.1.36) b. Piccolo Xpress analyzer (Serial Number 172.16.1.42) Also observed during an inspection of the refrigerated testing materials revealed the following expired test reagents: Piccolo Lipid Panel; Lot number 0433AC3; Expiration date 10/21/2021; 6 individual packages and 2 boxes of 10 packages Piccolo Brain Natriuretic Peptide (BNP) Panel; Lot number 0511AC0; Expiration date 11/19/2021; 1 box of 10 packages Piccolo Comprehensive Metabolic Panel (CMP); Lot number 0474BB6; Expiration date 11/19/2021; 7 individual packages and 7 boxes of 10 packages 2. Review of manufacturer's instructions stated the following: a. Each Piccolo Xpress Panel package inserts stated, " ...Reagent discs may be used until the expiration date included on the package ..." b. Piccolo Xpress User Manual (PN 1100-7108-1 Manual Text, Rev D) stated, "Physical and Environmental Specifications: Humidity 8 -80 % relative humidity noncondensing ..." c. Afinion 2 User Manual (1117003. Rev A 05/2020) stated, "Relative Humidity: 10 - 80%, non-condensing" d. Afinion 2 HbA1c Control package insert (REF 1116975) stated, "Test Procedure ... Allow the control material to reach ambient operating temperature 18 -30 C (64 - 86 F) before use, which takes approximately 45 minutes ..." 3. Review of the laboratory's</p> |

environmental records from October 1, 2021 through January 20, 2022 revealed the laboratory failed to define an acceptable relative humidity range to ensure manufacturer's criteria for the Afinion 2 and Piccolo Xpress analyzers. Further review of the laboratory's environmental records from October 1, 2021 through January 20, 2022 revealed an acceptable room temperature range of 15 - 25 C. The laboratory failed to ensure the laboratory's temperature range met acceptable temperature criteria for the Afinion 2 HbA1c control material (18 - 30 C). 4. During an interview on 01/20 /2022 at 12:20 pm in the laboratory area, the medical assistants present confirmed that the Piccolo test reagents were expired and that the laboratory failed to define acceptable criteria for relative humidity and room temperature. This confirmed the above findings.