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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 29D2166411 | (X3) Date Survey Completed 01/15/2020 |
| Name of Provider or Supplier Whasn-Central Laboratory | Street Address, City, State 6250 N Durango Dr, Las Vegas, NV | |
| 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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| D0000 | <p>This Statement of Deficiencies was created as a result of an on-site initial CLIA survey conducted at your facility on January 15, 2020. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.</p> |
| D5401 | <p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the director approved policy and procedure manual regarding the verification of new instruments, a review of the results and summary for the verification of the Beckman Coulter DXI 800 immunoassay analyzer and an interview with the laboratory manager, the laboratory failed to follow the policy for the verification of new instrumentation. Findings include: 1. The laboratory failed to follow the director approved policy for the verification of the Beckman Coulter DXI 800 in determining accuracy by running a minimum of twelve samples for each analyte that is to be verified before performing patient testing. 2. According to the Alternate Method Comparison Summary, there were eight samples run for the analyte DHEA-S, there were five samples run for the analyte Ferritin, there were eight samples run for the analyte TPO Antibody and there were three samples run for the analyte Vitamin B-12. This was confirmed by the laboratory manager on January 15, 2020 at approximately 2:00 PM. The laboratory performs approximately 4,856 Chemistry and 144 General Immunology patient laboratory tests annually.</p> |