

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D2176955	(X3) Date Survey Completed 11/06/2020
Name of Provider or Supplier Sterling Urgent Care	Street Address, City, State 2761 Commerical Way, Rock Springs, WY	
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
D5305	<p>TEST REQUEST CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.</p> <p>This STANDARD is not met as evidenced by: . Based on patient test records review, lack of documentation, and interview with staff, the laboratory failed to include gender in the test request information as needed to ensure the correct normal range is used in reporting hemoglobin and hematocrit results. The laboratory performs approximately 0-2 tests per day. Findings include: 1. Patient test requisition for patient #0030152 collected on 09/23/2020 at 10:35 A.M. failed to include the patient's gender. 2. In an interview with the laboratory manager on 11/05/2020 at approximately 11:50 A.M. the laboratory manager confirmed the test request did not solicit the patient's gender. .</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p>

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

. Based on procedure manual review, lack of documentation, and interview with staff, the laboratory director failed to sign and date the current procedure manual as approved for routine chemistry, endocrinology, and hematology tests. The laboratory performed approximately 1800 tests per year. Findings include: , 1. Procedure manual review failed to include the director's signature and the date the procedure manual was approved for routine chemistry, (Prostate Specific Antigen), and Endocrinology, (Thyroid Stimulating Hormone, Free Thyroxine, and Testosterone) tests performed on the FRENDA analyzer and for Complete Blood Cell Count tests performed on the Sysmex Poch 100i analyzer. 2. In an interview conducted on 11/05/2020 at approximately 1:00 P.M., the laboratory manager confirmed the director had not approved the procedure manual for each non-waived test performed in the laboratory. Based on Individualized Quality Control Plan (IQCP) review, patient test records review, lack of documentation, and interview with staff, the laboratory director failed to sign and date the IQCP as approved for 4 of 4 tests performed, Thyroid Stimulating Hormone (TSH), Free Thyroxine (FT4), Testosterone, and Prostate Specific Antigen (PSA). Findings include: 1. The laboratory developed an IQCP for TSH, FT4, Testosterone, and PSA moderate complexity testing performed on the FRENDA analyzer. 2. A. Patient test records review included patient 032394 TSH test performed on 06/10/2020. Quality control for TSH lot number 409014 testing was performed on 05/25/2020. B. Patient test records review included patient 9579 TSH test performed on 09/08/2020. Quality control for TSH lot number 409014 was performed on 05/25/2020. C. Patient test records review included patient 9579 Testosterone on 09/08/2020. Quality control for Testosterone was performed on lot number 409029 on 07/1/2020. 3. The IQCP was not dated as approved prior to the survey on 11/05/2020 4. In an interview conducted on 11/05/2020 at approximately 12:45 P.M., the laboratory manager confirmed the IQCP lacked the director's approval date. .

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

. Based on test package insert review, lack of documentation, and lack of a Food and Drug Administration (FDA) Emergency Use Authorization (EUA) test approval and Clinical Laboratory Improvement Amendments (CLIA) test categorization, and interview with staff, the laboratory failed to verify the Zhejiang Orient Gene Biotech

COVID - 19 IgG/IgM Rapid Test's manufacturer's performance specifications for the qualitative presence or absence of CoViD 19 IgG and/or IgM antibodies. The laboratory performed approximately 168 tests between 07/17/2020 and 10/08/2020. Findings include: 1. The package insert review failed to include the CLIA test categorization. 2. The laboratory failed to document test verification of performance specifications to include accuracy, precision, analytical specificity and analytical sensitivity. 3. Patient test records review included a list of approximately 168 patients tested for the presence or absence of CoViD 19 IgG and/or IgM antibodies. 4. In a telephone interview with the laboratory manager on 11/06/2020 at approximately 5:00 P.M., the manager stated the test was purchased as being EUA approved for waived testing synonymous with Healgen CoViD 19 antibody testing for IgG and IgM. The FDA list of EUA for CoViD 19 serology tests did not include a Zhejiang Orient Gene Biotech COVID -19 IgG/IgM test, nor was it listed as being the same test with a different name with the Healgen tests as claimed by the manager. .

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 test records review, CoViD 19 IgG/IgM package insert review, Food and Drug Administration Emergency Use Authorization list review, lack of documentation and interview with staff, the laboratory director failed to qualify as a high complexity director for CoViD 19 Antibody testing in use. The laboratory performed approximately 169 tests from 07/16/2020 to 11/06/2020. (See D6078) .

D6078

LABORATORY DIRECTOR QUALIFICATIONS
CFR(s): 493.1443

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high

complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:

. Based on test records review, CoViD 19 IgG/IgM package insert review, Food and Drug Administration (FDA) Emergency Use Authorization list review, lack of documentation, and interview with staff, the laboratory director failed to qualify as a high complexity director for CoViD 19 Antibody testing. The laboratory performed approximately 169 tests from 07/16/2020 to 11/06/2020. Findings include: 1. Test records review included documentation the laboratory performed CoViD 19 IgG and IgM tests from July 17, 2020 to November 06, 2020 for approximately 169 patients. 2. CoViD 19 IgG/IgM Package insert stated the name of the test was Zhejiang Orient Gene Biotech for CoViD 19 IgG/gM and test kit box stated the same. 3. FDA list of EUA tests failed to include the Zhejiang Orient Gene Biotech IgG/IgM test. Tests that have not been categorized under an EUA default to CLIA high complexity tests. 4. The laboratory lacked documentation the director qualified as a high complexity laboratory director. 5. In an interview conducted on 11/06/2020 at approximately 5:00 P.M. laboratory staff confirmed the test was not the test stated on the CMS 116 application as the Healgen CoViD 19 IgG/IgM. Laboratory staff stated they believed the test to have an EUA as the kit was labeled "For Emergency Use Authorization Only". .

D6108

LABORATORY TECHNICAL SUPERVISOR
CFR(s): 493.1447

The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

This CONDITION is not met as evidenced by:

. Based on test records review, CoViD 19 IgG/IgM package insert review, Food and Drug Administration Emergency Use Authorization list review, lack of documentation, and interview with staff, the laboratory technical supervisor failed to qualify as a high complexity technical supervisor for CoViD 19 Antibody testing. The laboratory performed approximately 169 tests from 07/16/2020 to 11/06/2020. (See D6109) .

D6109

TECHNICAL SUPERVISOR QUALIFICATIONS
CFR(s): 493.1449

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the

specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

. Based on test records review, CoViD 19 IgG/IgM package insert review, Food and Drug Administration (FDA) Emergency Use Authorization list review, lack of documentation and interview with staff, the laboratory failed to have a qualified high complexity technical supervisor for high complexity CoViD 19 Antibody testing. The laboratory performed approximately 169 tests from 07/16/2020 to 11/06/2020. Findings include: 1. Test records review included documentation the laboratory performed CoViD 19 IgG and IgM tests from July 17, 2020 to November 06, 2020 for approximately 169 patients. 2. CoViD 19 IgG/IgM Package insert stated the name of the test was Zhejiang Orient Gene Biotech for CoViD 19 IgG/IgM and test kit box stated the same. 3. FDA list of EUA tests failed to include the Zhejiang Orient Gene Biotech IgG/IgM test. Tests that have not been categorized under an EUA are high complexity tests. 4. The laboratory lacked documentation the current technical consultant qualified as a high complexity laboratory technical supervisor. 5. In an interview conducted on 11/06/2020 at approximately 5:00 P.M., laboratory staff confirmed the test was not the test stated on the CMS 116 application as the Healgen CoViD 19 IgG/IgM. Laboratory staff stated they believed the test to have an EUA as the kit was labeled "For Emergency Use Authorization Only". .

D6141

GENERAL SUPERVISOR

CFR(s): 493.1459

The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.

This CONDITION is not met as evidenced by:

. Based on lack of a stated qualified general supervisor on the CMS 209 personnel form, Zhejiang Orient Gene Biotech for CoViD 19 IgG/IgM Rapid Tests antibody package insert review, lack of documentation, and interview by phone with the laboratory manager, the laboratory failed to have a qualified General Supervisor. (See D6142) .

D6142

GENERAL SUPERVISOR QUALIFICATIONS

CFR(s): 493.1461

The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.

This STANDARD is not met as evidenced by:

. Based on personnel records review, lack of documentation, and confirmation by the laboratory manager, the laboratory lacked a qualified general supervisor for

	<p>performing Zhejiang Orient Gene Biotech CoViD 19 IgG/IgM tests. Findings include:</p> <ol style="list-style-type: none"> 1. The laboratory did not list a general supervisor on the CMS 116 personnel form. Personnel qualification records reviewed failed to include an individual qualified to supervise high complexity general immunology testing. 2. In an interview conducted by phone on 11/06/2020 at approximately 5:00 P.M. the lab manager confirmed the laboratory did not have a designated general supervisor for high complexity CoViD 19 general immunology testing. .
<p>D6168</p>	<p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.</p> <p>This CONDITION is not met as evidenced by:</p> <ul style="list-style-type: none"> . Based on testing personnel records review, lack of documentation, and interview with staff, the laboratory failed to have testing personnel qualified to perform high complexity CoViD 19 IgG/IgM tests. (See D6170) .
<p>D6170</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a)</p> <p>Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.</p> <p>This STANDARD is not met as evidenced by:</p> <ul style="list-style-type: none"> . Based on personnel records review, lack of documentation, and interview with staff, the laboratory failed to ensure 4 of 5 testing personnel qualified as high complexity testing personnel for performing CoViD 19 IgG/ IgM antibody testing. Findings include: 1. Testing personnel test records reviewed lacked documentation 4 of 5 testing personnel qualified as high complexity testing personnel. (A, B, C, E, and F). 2. The laboratory performed high complexity CoViD 19 IgG/IgM testing for approximately 169 patients using a test kit that did not have an Emergency Use Authorization or CLIA test categorization defaulting to a high complexity test. 3. In an interview conducted by phone on 11/06/2020 at approximately 5:00 P.M., the lab manager confirmed 4 of 5 testing personnel did not have qualifications for high complexity testing personnel. .