

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2183180	(X3) Date Survey Completed 03/30/2021
Name of Provider or Supplier Olympus Health And Performance	Street Address, City, State 1414 S Foothill Drive Suite D, Salt Lake City, UT	
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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Analytic Systems was not met. The laboratory failed to follow manufacturer's instructions for Healgen COVID-19 IgG/IgM Rapid Test Cassette specimen collection (see D5411), monitor and document room temperature (see D5413), verify test performance specifications (see D5423), establish control procedures (see D5445).</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on manufacturer's instruction review, Standard Operating Procedure (SOP) review, observation of testing, and interview with the technical consultant and laboratory director, manufacturer's instructions for Healgen COVID-19 IgG/IgM</p>

Rapid Test Cassette were not followed for specimen collection. Findings include: 1. Manufacturer's instructions for Healgen COVID-19 IgG/IgM Rapid Test Cassette state acceptable sample types are venous whole blood, serum or plasma. 2. Manufacturer's instructions for Healgen COVID-19 IgG/IgM Rapid Test Cassette state fingerstick specimens were not evaluated and were not recommended. 3. SOP instructions included directions to obtain patient specimens by fingerstick, and apply fingerstick sample directly to test cassette. 4. Test observation on 3/30/21 at approximately 12:30 p.m. included collection of a patient sample by fingerstick. 5. In an interview on 3/30/21 at approximately 1:00 p.m., the technical consultant and laboratory director confirmed that tests were performed by fingerstick.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on documentation review and interview with the technical consultant, the laboratory failed to monitor and document the room temperature where Healgen COVID-19 IgG/IgM Rapid Test Cassette is performed. Findings include: 1. No temperature log existed for the laboratory. 2. In an interview on 3/30/21 at approximately 10:30 a.m., the technical consultant confirmed that room temperature was not monitored in the laboratory.

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 manufacturer's instruction review, Standard Operating Procedure (SOP) review, direct observation, lack of documentation, and interview with the technical consultant and laboratory director, verification of performance specifications was not performed for Healgen COVID-19 IgG/IgM Rapid Test Cassette. The laboratory performs approximately 3,500 tests per year. Findings include: 1. Manufacturer's instructions for Healgen COVID-19 IgG/IgM Rapid Test Cassette stated acceptable

sample types as venous whole blood, serum or plasma. 2. Manufacturer's instructions for Healgen COVID-19 IgG/IgM Rapid Test Cassette stated fingerstick specimens were not evaluated for this test method. 3. An observation of testing on 3/30/21 at approximately 12:30 p.m. included performance of the test using a fingerstick sample. 5. No documentation of verification of performance specifications of fingerstick samples was present. 5. In an interview on 3/30/21 at approximately 1:00 p.m., the laboratory director and technical consultant confirmed that no test validation was performed.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on manufacturer's instruction review, Standard Operating Procedure (SOP) review, Individualized Quality Control Plan (IQCP) review, lack of quality control documentation, observation of testing, and interview with the technical consultant and laboratory director, the laboratory failed to establish control procedures for Healgen COVID-19 IgG/IgM Rapid Test Cassette. The laboratory performed approximately 3,500 tests annually. Findings included: 1. Healgen COVID-19 IgG/IgM Rapid Test Cassette kit did not include control material. 2. Manufacturer's instructions for Healgen COVID-19 IgG/IgM Rapid Test Cassette included the statement "Additional controls may be required according to guidelines or local, state, and or federal regulations (such as 42 CFR 493.1256)" 3. A review of the SOP did not include instructions to perform quality control. 4. A review of the IQCP plan did not include instructions for quality control performance. 5. There was no documentation that quality control was performed. 6. During an observation of testing, on 3/30/21, at approximately 12:30 p.m., no quality control was performed. 7. During an interview, on 3/30/21 at approximately 1:00 p.m., the technical consultant and laboratory director confirmed that no quality control material had been purchased or tested.

D6070

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
Based on standard operating procedure (SOP) review, observation of testing, and an interview with the technical consultant, the laboratory SOP for Healgen COVID-19 IgG/IgM Rapid Test Cassette was not followed. Findings include: 1. Healgen COVID-19 IgG/IgM Rapid Test Cassette SOP review included instructions that test cassette

must be labeled with patient identifier. 2. Test observation on 3/30/21 at approximately 12:30 p.m., included observation of testing personnel 1 (TP1) performing a Healgen COVID-19 IgG/IgM Rapid Test Cassette. TP1 performed the test on an unlabeled cassette placed on top of the patient report paper. 3. In an interview on 3/30/21 at approximately 1:00 p.m., the laboratory director and technical consultant both confirmed that SOP was not followed.

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 the number and severity of the deficiencies cited herein, the Condition: Laboratories performing high complexity testing was not met. The laboratory failed to have a qualified laboratory director (see D6078), a qualified technical supervisor (see D6108), qualified testing personnel (see D6171), and a general supervisor (see D6141). The Healgen COVID-19 IgG/IgM Rapid Test Cassette was not validated or performed following manufacturer's instructions as required for accurate and reliable results (see D5411 and D5423).

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 curriculum vitae and certification review, and interview with the laboratory director and technical consultant, the laboratory director was not qualified to direct a high complexity laboratory. Findings include: 1. Laboratory did not follow test manufacturer's instructions for use for Healgen COVID-19 IgG/IgM Rapid Test Cassette. 2. Laboratory director did not have one year of laboratory training, 2 years' experience directing or supervising high complexity testing, or hold an HHS approved board certification. 3. In an interview on 3/30/21 at approximately 1:00 p.m., the technical consultant and laboratory director confirmed that they did not follow the test manufacturer's instructions for use for Healgen COVID-19 IgG/IgM Rapid Test Cassette.

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 record review, the laboratory did not have a qualified technical supervisor on staff. Findings include: 1. Personnel listed on form CMS-209 did not hold qualifications required for a technical supervisor.

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 record review, the laboratory did not have a qualified general supervisor on staff. Findings include: 1. No personnel listed on form CMS-209 identified as a general supervisor. 2. Personnel listed on form CMS-209 did not hold qualifications required for a general supervisor.

D6171

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory

science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on personnel qualification review and interview with laboratory director and technical consultant, testing personnel did not meet requirements to perform high complexity testing. Findings include: 1. Test manufacturer's instructions for use for

Healgen COVID-19 IgG/IgM Rapid Test Cassette were not followed. 2. No testing personnel had qualifications that met requirements for high complexity testing. 3. In an interview on 3/30/21 at approximately 1:00 p.m., the laboratory director and technical consultant confirmed that manufacturer's instructions for use for Healgen COVID-19 IgG/IgM Rapid Test Cassette were not being followed, and testing personnel were not qualified for high complexity testing.