

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1025951	(X3) Date Survey Completed 05/11/2021
Name of Provider or Supplier Medcare Group	Street Address, City, State 6975 West 130th Street, Parma Heights, OH	
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
D1000	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c)</p> <p>Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.</p> <p>This STANDARD is not met as evidenced by: Based on the laboratory's certificate of compliance registration date, an email from the Laboratory Consultant (LC), and an interview with the Laboratory Director (LD), the laboratory failed to obtain a registration, accreditation or compliance certificate before performing and reporting patient results for tests not categorized as waived. This deficient practice had the potential to affect 558 patients. Findings Include: 1. An email sent 04/29/2021 at 1:58 PM to the inspector from the LC stated troponin/CK-MB/myoglobin serum testing began 04/05/2019. 2. Review of the laboratory's certificate of registration confirmed 06/17/2020 as the date of registration. 3. Review of patient logs from 08/01/2019 through 05/27/2020 revealed troponin/CK-MB /myoglobin serum test results were reported. 4. The LD confirmed the laboratory</p>

	<p>tested troponin/CK-MB/myoglobin prior to registering for a certificate of compliance on 06/17/2020. The interview occurred on 05/11/2021 at 10:15 AM. CK-MB: creatine kinase muscle brain</p>
<p>D2000</p>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and an interview with the Laboratory Director (LD), the laboratory failed to enroll in a proficiency testing (PT) program for the sub-specialties of virology, chemistry and bacteriology. All patient virology, chemistry and bacteriology testing performed in this laboratory from 06/17/2020 through 03/01/2021 had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to enroll in a proficiency testing (PT) program for the regulated toxicology analytes. (Refer to D2001)</p>
<p>D2001</p>	<p>ENROLLMENT CFR(s): 493.801(a)(1)(2)(i)</p> <p>The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS;</p> <p>This STANDARD is not met as evidenced by: Based on an interview with the Laboratory Director (LD), and review of proficiency testing records (PT), the laboratory failed to enroll in a proficiency testing program for the regulated virology, chemistry and bacteriology analytes. All patient virology, chemistry and bacteriology testing performed in this laboratory from 06/17/2020 through 03/01/2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of PT documents and enrollment found no records. 2. The Inspector requested the laboratory's 2020 PT documents and enrollment records for virology, chemistry and bacteriology from the LD. The LD confirmed the laboratory was not enrolled with a PT provider for virology, chemistry and bacteriology in 2020 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 05/11/2021 at 10:49 AM. .</p>
<p>D5403</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test</p>

procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Laboratory Consultant (LC), the laboratory failed to include in their policies and procedures the COVID-19 antibody, troponin/CK-MB/myoglobin and chlamydia requirements for specimen labeling, processing, referral, criteria for specimen acceptability and rejection, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable. This deficient practice had the potential to affect 5559 patients tested. Findings Include: 1. Review of the laboratory's policies and procedures titled "Quality Assurance Procedure Manual - Quality Assessment - Analytical Phase" signed by the LD but not dated on the date of inspection failed to find a policy and procedure for the COVID-19 antibody, troponin/CK-MB/myoglobin and chlamydia requirements for specimen labeling, processing, referral, criteria for specimen acceptability and rejection, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable. 2. The inspector requested a policy and procedure for the COVID-19 antibody, troponin/CK-MB/myoglobin and chlamydia requirements for specimen labeling, processing, referral, criteria for specimen acceptability and rejection, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable from the LC. The LC confirmed there was no policy and procedure and was unable to provide the requested documents. The interview occurred 05/11/2021 at 11:15 AM. CK/MB : creatine kinase muscle/brain

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

ITEM 1: Based on document reviews and an interview with the Laboratory Consultant (LC), the laboratory failed to follow written policies and procedures for procedure

manual reviews in the post analytic systems. This deficient practice had the potential to affect 39,754 patients tested. Findings include: 1. Review of the laboratory's policy and procedures titled "Quality Assurance Procedure Manual - Quality Assessment - Analytical Phase" signed by the LD but not dated found the following statement: "Policies and procedures will be reviewed annually. Each manual will be reviewed by the laboratory supervisor for changes, updates and additional or discontinued procedures..." 2. Further review of the policies and procedures revealed no documentation of reviews and the following procedures not relevant to the laboratory tests: "Verification of Performance Specifications" "Instrument Calibration" "Instrument Calibration Verification" "Reference Range Checks" 3. An interview with the LC on 05/11/2021 at 12:40 PM confirmed the laboratory failed to follow the procedure manual for annual review and the manual contained procedures not relevant to testing. Note: The "Quality Assurance Procedure Manual - Quality Assessment - Analytical Phase" contained post analytical laboratory functions. ITEM 2: Based on document review and interviews with the Laboratory Consultant (LC), the laboratory failed to follow the procedure manual for monthly and annual quality control reviews. This deficient practice had the potential to affect 39,754 patients tested. Findings include: 1. Review of the laboratory's policy and procedures titled "Quality Assurance Procedure Manual - Quality Assessment - Analytical Phase" signed by the LD but not dated found the following statement: " Quality control records and logs will be reviewed monthly..." 2. Review of quality control records and logs did not find any documentation of review. 3. The inspector requested documentation of quality control record and log reviews from the LC on 05/11/2021 at 12:40 PM and the LC confirmed no reviews had been performed or documented. ITEM 3: Based on document review and interviews with the Laboratory Consultant (LC), the laboratory failed to follow the procedure manual for monthly and annual reviews. This deficient practice had the potential to affect 39,754 patients tested. Findings include: 1. Review of the laboratory's policy and procedures titled "Quality Assurance Procedure Manual - Quality Assessment - Post Analytical Phase" signed by the LD but not dated found the following statement: "All testing performed by the Medical Assistant Staff will be reviewed annually. Each month, all records for one of the MA tests will be reviewed to verify the testing has been properly documented in each form used by the practice. A different test will be evaluated each month, resulting in each test being reviewed once each year." 2. The inspector requested documentation of records reviewed for 2020 and 2021 from the LC on 05/11/2021 at 12:45 PM and the LC confirmed no reviews had been performed or documented. ITEM 4: Based on document review and interviews with the Laboratory Consultant (LC), the laboratory failed to follow the procedure manual for monthly and annual reviews. This deficient practice had the potential to affect 39,754 patients tested. Findings Include: 1. Review of the laboratory's policy and procedures titled "Quality Assurance Procedure Manual - Quality Assessment - Post Analytical Phase" signed by the LD but not dated found the following statement: "Test reports will be evaluated on an annual basis. Twenty random test reports (ten from in-house lab, ten from send out lab) will be generated in the EMR and reviewed for the following:..." 2. The inspector requested documentation of records reviewed for 2020 and 2021 from the LC on 05/11/2021 at 12:45 PM and the LC confirmed no reviews had been performed or documented.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Item 1: Based on record review and an interview with the Laboratory Director (LD), and the Laboratory Consultant (LC), the Laboratory Director failed to ensure that eight out of nine Testing Personnel (TP) TP #1 was trained and had demonstrated they could perform testing procedures reliably to provide and report accurate results prior to performing patient testing. This deficient practice had the potential to affect six patients tested. Findings Include: 1. Review of the laboratory's policies and procedures, approved/signed by the LD but not dated, and provided on the date of the inspection, found the following instructions: "Each employee performing laboratory testing (Laboratory and MA staff) will be evaluated every six months during the first year of employment and annually thereafter. Each employee's personnel folder will be checked to verify proof of education, Laboratory Competency Checklists..." 2. An email sent to the inspector on 04/29/2021 at 1:58 PM by the LC stated Troponin/CK-MB/Myoglobin Serum RapiCard InstaTest testing began 04/05/2019. 3. The Inspector requested the laboratory's Troponin/CK-MB/Myoglobin Serum RapiCard InstaTest training and initial demonstration of competency documentation for TP #1 from the LC. The LC provided the following initial competency assessments: TP Initial Competency Assessment TP #1 08/14/2019 4. The LD and the LC confirmed the laboratory did not document training or initial demonstration of competency in order to reliably provide and report accurate results prior to patient testing for TP#1 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 05/11/2021 at 10:33 AM. Item 2: Based on record review and an interview with the Laboratory Director (LD), and the Laboratory Consultant (LC), the Laboratory Director failed to ensure that two out of nine Testing Personnel (TP) #1 and TP #8 were trained and had demonstrated they could perform testing procedures reliably to provide and report accurate results prior to performing patient testing. This deficient practice had the potential to affect 22 patients tested by TP #1 and 41 patients tested by TP #8. Findings Include: 1. Review of the laboratory's policies and procedures, approved/signed by the LD but not dated, and provided on the date of the inspection, found the following instructions: "Each employee performing laboratory testing (Laboratory and MA staff) will be evaluated every six months during the first year of employment and annually thereafter. Each employee's personnel folder will be checked to verify proof of education, Laboratory Competency Checklists..." 2. The Inspector requested the laboratory's UNscience covid antibody test training and initial demonstration of competency documentation for TP #1 and TP #8 from the LC. The LC provided the following initial competency assessments: TP Initial Competency Assessment TP #1 08/14/2019 TP #8 12/08/2020 4. The LD and the LC confirmed the laboratory did not document training or initial demonstration of competency in order to reliably provide and report accurate results prior to patient testing for TP #1 and TP #8 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 05/11/2021 at 10:33 AM.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

The laboratory director is responsible for the overall operation and administration of

the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
 Based upon record review and an interview with the Laboratory Consultant (LC), the Laboratory Director (LD) failed to specify the duties and responsibilities of each person listed on the Form CMS 209. This deficient practice had the potential to affect 39,754 patients tested. Findings include: 1. Review of the Form CMS 209 found one individual listed as the technical consultant and nine individuals listed as testing personnel. 2. Review of policies and procedures failed to find evidence of the duties and responsibilities for the technical consultant and each testing personnel in writing by the laboratory director. 3. The LC confirmed the LD failed to specify in writing the duties of all personnel listed on the Form CMS 209. The interview occurred 05/11 /2021 at 12:20 PM.

D6168

TESTING PERSONNEL
 CFR(s): 493.1487

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.

This CONDITION is not met as evidenced by:
 Based on record review and interviews with the Laboratory Director (LD) and the Laboratory Consultant (LC), the laboratory failed to ensure Testing Personnel (TP) #2, TP #5, TP #6 and TP #8 met the qualification requirements of 493.1489 for high complexity testing procedures. This deficient practice had the potential to affect 5,487 patients tested. Findings Include: 1. The laboratory failed to ensure TP #2, TP #5, TP #6 and TP #8 met the minimum qualification requirements of 493.1489 for high complexity testing procedures. (Refer to D6171)

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 record review and interviews with the Laboratory Director (LD) and Laboratory Consultant (LC), the laboratory failed to ensure Testing Personnel (TP) #2, TP #5, TP #6 and TP #8 met the minimum qualification requirements of 493.1489 for high complexity testing procedures. This deficient practice had the potential to affect 5,487 patients tested. Findings Include: 1. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 04/16/2021, found nine individuals listed and certified by the LD to perform high complexity testing procedures. 2. Review of education documentation revealed four out of nine TP, TP #2, TP #5, TP #6 and TP #8, obtained a high school diploma which does not meet the

minimum qualification requirements for high complexity TP. 3. The Inspector requested any additional education documents for TP #2, TP #5, TP #6 and TP #8, which meet the high complexity TP qualification requirements from the LC. The LC confirmed no other education documents were available and was unable to provide the requested documents on the date of inspection to prove high complexity TP qualification requirements were met for TP #2, TP #5, TP #6 and TP #8. The interview occurred on 05/11/2021 at 10:15 AM.