

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D2081885	(X3) Date Survey Completed 05/24/2019
Name of Provider or Supplier Numale New Mexico, Sc	Street Address, City, State 7920 Wyoming Blvd Ne, Ste B-2, Albuquerque, 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
D0000	During a Recertification survey completed on 05/24/19 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following condition: 42 CFR Part 493.1403 Laboratory Director, moderate complexity 42 CFR Part 493.1409 Technical Consultant, moderate complexity
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on the review of the CMS Form 209 Personnel Report Form, personnel records, and interviews with laboratory staff, the laboratory director failed to provide overall management and direction of the laboratory. Findings are: The Laboratory Director did not delegate the Technical Consultant responsibilities in writing to a qualified technical consultant. See D6032</p>
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p> <p>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</p>

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 on review of the CMS Form 209 Laboratory Personnel Report Form, personnel records, and interview with the Director of Operations, the Laboratory Director did not delegate the Technical Consultant responsibilities in writing to a qualified technical consultant. Findings are: A. Review of the original CMS Form 209 signed by the Laboratory Director on 05/20/19 did not list anyone other than himself as the Technical Consultant. B. Review of personnel records revealed documentation that laboratory staff other than the Technical Consultant performed competency evaluations for 2 (TP #1 and TP #3) of 2 of testing personnel employed since 2018. C. During interview on 05/23/19 at 4:35 pm, the Director of Operations stated the laboratory did not have a "Delegation of Authority" document that authorized the Corporate Compliance Manager(or other laboratory staff) to perform the duties of the Technical Consultant.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on the review of the CMS Form 209 Personnel Report Form, personnel records, e-mail and interviews with laboratory staff, the Technical Consultant failed to provide technical oversight of the laboratory. Findings are: The Technical Consultant failed to either personally perform or delegate to a qualified person (See D6035) the following responsibilities: A. Establish an effective quality control program for the TOSOH Immunoassay analyzer. See D6042 B. Perform competency evaluations including direct observation of testing personnel skills or delegate this responsibility to another qualified technical consultant for 2 (TP #1 & TP #3) of 2 current testing personnel hired in 2018. See D6046 and D6047

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant 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)(i) 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; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical

oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:
Based on the review of laboratory policy, emails and interview with laboratory staff, the Technical Consultant delegated the oversight of the Quality Control program and competency of testing personnel to laboratory personnel that did not meet the educational requirements for Technical Consultant. Findings are: A. The Corporate Compliance Manager was responsible for the laboratory's quality control program. 1. During interview on 05/23/19 at 02:45 pm, the laboratory's Director of Operations stated that the Corporate Compliance Manager was responsible for establishing quality control ranges for the TOSOH 360 Immunoassay analyzer. 2. Review of an email dated 05/24/19 from the Director of Operations indicated the Corporate Compliance Manager did not meet the educational requirement of a Technical Consultant and no documentation was provided to establish her credentials. 3. Review of the laboratory's undated "Quality Control and Assessment Policy" indicated "Documentation and review of the Quality Controls shall be done at least weekly and monthly by laboratory staff and Laboratory Director/Technical Consultant." B. There was no documentation that the Technical Consultant performed competency evaluations or delegated the responsibility to qualified staff. See D6046 and D6047

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:
Based on the review of emails, personnel records quality control policies, Westgard Rules and interviews with laboratory staff, the Technical Consultant failed to establish an effective quality control program for the TOSOH Immunoassay analyzer. Findings are: A. The laboratory failed to use an accurate interpretation of "Westgard Rules"(a

set of guidelines used to assess the acceptability of quality control results) in the laboratory's undated Quality Control and Assessment Policy. 1. Review of the laboratory's "Quality Control and Assessment Policy," reviewed by the Laboratory Director on 12/15/17, indicated the laboratory followed 3 Westgard rules, 1-2S, 2-2S, and 1-3S for daily quality control assessment. The policy stated, "Reject the run if: a) both controls are greater than 2 SD (Standard Deviation - a measure that is used to quantify the amount of variation) from the mean (2-2S Rule) b. one control is greater than 2 SD and less than 3 SD on two consecutive runs (2-2S Rule) c. one control is greater than 3 SD from the mean (1-3S Rule) 2. Review of the website www.westgard.com indicated that the Westgard rules should be applied in the order shown in the decision charts and the laboratory should not "mix and match in a random fashion" when building a quality control program. The chart indicated that rejection of a run should occur if: 1 control is outside of 3 SD (1-3S) OR 2 consecutive values are outside the same 2 SD (2-2S). 3. Further review of the laboratory's "Quality Control and Assessment Policy" revealed two different interpretations of the 2-2S Rule. Neither match the interpretation on the published Westgard decision charts. B. The laboratory failed to develop quality control ranges based on the data obtained in the laboratory. 1. During interview on 05/23/19 at 02:46 pm, the Corporate Compliance Manager stated that the quality control ranges were established for the corporation, not individual laboratory sites. 2. Review of the manufacturer's instructions for the use of the BioRad Immunoassay Plus Quality Control revealed: "The mean values and corresponding +/- 3 SD ranges in the Assignment of Values Data Charts were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed values during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications." 3. Review of April 2019 Quality Control data revealed the laboratory did not conduct studies to develop the acceptable ranges for the current lot of quality controls but used the manufacturer's ranges. a. Lot 40971 Low control Manufacturer 3 SD range 158 - 293 pg/mL (picograms/milliliter) Laboratory 3 SD range 158 - 293 b. Lot 40972 Normal control Manufacturer 3 SD range 438 - 813 pg/mL Laboratory 3 SD range 438 - 813 c. Lot 40973 High control Manufacturer 3 SD range 1019 - 1893 pg/mL Laboratory 3 SD range 1019 - 1893 C. Review of the laboratory's established 3 SD ranges (from January-February and October-November 2018 quality control logs) revealed that they did not fall within the manufacturer's stated 3 SD range for Estradiol. The logs indicated that a range study was performed April 2017 - May 2017 for these lots of controls. a. Lot 40931 Low control expiration date 02/28/2019 Manufacturer 3 SD range 185 - 343 pg/mL (picograms/milliliter) Laboratory 3 SD range 165.4 - 307 b. Lot 40932 Normal control expiration date 02/28/2019 Manufacturer 3 SD range 513 - 952 Laboratory 3 SD range 506.7 - 940.5 c. Lot 40933 High control expiration date 02/28/2019 Manufacturer 3 SD range 1058 - 1964 Laboratory 3 SD range 1048.7 - 1947.5 D. Review of 2018-2019 quality control graphs revealed no documentation of review by the Technical Consultant. The only documentation was troubleshooting steps taken by laboratory staff (not identified).

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of

all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on the review of personnel records, CMS Form 209, job descriptions, laboratory policies, and interview with the Director of Operations, the Technical Consultant failed to perform the competency evaluations for 2 (TP #1 & TP #3) of 3 (TP #1- TP#3) current testing personnel. Findings are: There was no documentation that the Laboratory Director (Technical Consultant) performed competency evaluations or delegated the responsibility to a qualified technical consultant. A. Review of the original CMS Form 209, Personnel Report Form, dated 05/20/19, indicated the Laboratory Director also performed the duties of the Technical Consultant. B. Review of personnel records revealed that competency evaluations were performed by laboratory personnel that did not meet the qualifications of a Technical Consultant. 1. TP (Testing Person) #1 was hired on 09/10/18 as the Office Manager. TP #1 qualified as a testing person under 42 CFR Part 493.1423 (b)(3), high school diploma or equivalent plus documented training. The 6-month competency assessment dated 05/21/19 was performed by the Corporate Compliance Manager and signed by the Laboratory Director on 5/22/2019. No documentation was provided by the laboratory establishing the Corporate Compliance Officer's qualifications as a Technical Consultant, either in person during the survey on 05/23/19 or via email request on 05/24/19. 2. TP #3 was hired on 10/24/18 as a medical assistant. TP #3 qualified as a testing person under 42 CFR Part 493.1423 (b)(3), high school diploma or equivalent plus documented training. The 6-month competency assessment dated 05/21/19 was performed by TP #1 (a high school graduate) and signed by the Technical Consultant on 5/23/2019. C. Review of the laboratory's undated "Orientation (sic), Training and Competency" policy did not have a specific requirement for the 6-month competency but indicated the "Laboratory Director, Supervisor or Technical Consultant may assess further evaluation and competency through the facility administrator or other persons on site in authority."

D6047

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:

Based on the review of personnel records, job descriptions, laboratory policies, and email, the Technical Consultant failed to directly observe the testing personnel skills or delegate this responsibility to another qualified technical consultant for 2 (TP #1 & TP #3) of 2 current testing personnel hired in 2018. Findings are: A. There was no documentation that the Laboratory Director (Technical Consultant) personally observed the testing personnel as part of the competency evaluation or delegated the responsibility to a qualified technical consultant. 1. Review of the original CMS Form 209, Personnel Report Form, dated 05/20/19, indicated the Laboratory Director also performed the duties of the Technical Consultant. 2. Review of personnel records revealed that training and competency evaluations were not performed by the Laboratory Director/Technical Consultant for current testing personnel hired in 2018. a. TP (Testing Person) #1 was hired on 09/10/18 as the Office Manager. TP #1

qualified as a testing person under 42 CFR Part 493.1423 (b)(3), high school diploma or equivalent plus documented training. i. According to a "Laboratory Staff Job Description," she was authorized by the Laboratory Director via electronic signature to perform testing on "11/15/2018 1:22:56 PM PST." ii. The initial training for TP #1 was dated 11/06/18. It was electronically signed by the Laboratory Director on "11/26/2018 10:01:33 AM PST." iii. The 6-month competency assessment (including observation of skills), dated 05/21/19 was performed by the Corporate Compliance Manager and signed by the Laboratory Director on 5/22/2019. No documentation was provided by the laboratory establishing the Corporate Compliance Officer's qualifications as a Technical Consultant, either in person during the survey on 05/23/19 or via email request on 05/24/19. b. TP #3 was hired on 10/24/18 as a medical assistant. TP #3 qualified as a testing person under 42 CFR Part 493.1423 (b)(3), high school diploma or equivalent plus documented training. i. According to a "Laboratory Staff Job Description," he was authorized by the Laboratory Director via electronic signature to perform testing on "11/15/2018 1:22:56 PM PST." ii. The initial training for TP #3 was performed on 11/6/18. It was electronically signed by the Laboratory Director on "11/26/2018 10:01:33 AM PST." iii. The 6-month competency assessment (including observation of skills) dated 05/21/19 was performed by TP #1 (a high school graduate) and signed by the Laboratory Director/Technical Consultant on 5/23/2019. 3. Review of the laboratory's undated "Orientation(sic), Training and Competency" policy did not specifically address 6-month competency but indicated the "Laboratory Director, Supervisor or Technical Consultant may assess further evaluation and competency through the facility administrator or other persons on site in authority." 4. Review of an email dated 05/24/19 from the Director of Operations indicated, "We understand after our conversation yesterday that although [Corporate Compliance Manager] has multiple years of lab experience as well as supervisory experience in the lab she does not meet the requirements of technical consultant for due to not meeting the education requirement."