

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2086506	(X3) Date Survey Completed 01/21/2020
Name of Provider or Supplier Ibrahim S Elsheikh Md (Pediatric Care)	Street Address, City, State 7575 Northcliff Ave Suite 304, Brooklyn, 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
D2000	<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, the laboratory failed to enroll in a proficiency testing (PT) program for the sub-specialty of General Immunology. All patient Immunology testing performed in this laboratory from 11/19 /2019 to 01/21/2020 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 analyte immunoglobulin E (IgE); allergy testing. (Refer to D2001)</p>
D2001	<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>

This STANDARD is not met as evidenced by:
Based on record review and an interview with the Laboratory Director, the laboratory failed to enroll in a proficiency testing (PT) program for the regulated analyte immunoglobulin E (IgE); allergy testing. All patient immunology testing performed in this laboratory from 11/19/2019 to 01/21/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's Wisconsin State Laboratory Hygiene (WSLH) PT enrollment document did not find verification of enrollment for the analyte IgE which appears on Subpart I. 2. The Inspector requested the laboratory's PT enrollment records for IgE from the Laboratory Director. The Laboratory Director confirmed that the laboratory was not enrolled with a PT provider for IgE and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/21/2020 at 9:55 AM.

D2015

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:
Based on record review and an interview with the Laboratory Director, the laboratory failed to establish a policy and procedure for documenting the handling, preparation, processing, examination and each step in the testing and reporting of proficiency testing (PT) results. All patient testing performed in this laboratory had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find mention of any PT policies and procedures. 2. The Inspector requested the laboratory's PT policy and procedure from the Laboratory Director. The Laboratory Director confirmed the laboratory did not have an established PT policy and procedure for documenting the handling, preparation, processing, examination and each step in the testing and reporting of PT results and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/21/2020 at 9:55 AM.

D3031

RETENTION REQUIREMENTS
CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:

Based on record review and an interview with testing personnel (TP) #2, the laboratory failed to retain all analytic system activity records for the Medonic MSeries Hematology complete blood count (CBC) with five part automated differential (auto diff) test system. All patient CBC with auto diff testing from 10/31/2019 to 12/28/2019 were affected by this deficient practice. Findings Include: 1. TP#2 stated the laboratory's procedures in which the Medonic MSeries instrument printouts for patient CBC with auto diff test results were scanned into the patients electronic medical record (EMR) and the daily background checks and quality control (QC) printouts were kept in a three-ringed binder. No QC records were found for the following dates of laboratory operation: 2019 November 7, 14, 16, 19, 21 December 5, 7, 12, 14, 17, 19, 21, 23, 24, 26, 27, 28 2020 January 2, 4, 9, 16, 18, 21 2. Direct observation of the laboratory, on 01/21/2020 at 12:15 PM, did not find any instrument maintenance and reagent lot number activities recorded and retained from 10/31/2019 to 01/21/2020. 3. Review of the laboratory's Medonic MSeries Hematology on-board instrument records, provided on the date of the inspection, revealed records of maintenance, a reagent log, calibration, QC and patient test results; however all records were missing from the date of instrument implementation on 10/31/2019 to 12/28/2019. 4. The Inspector requested the laboratory's 2019 and 2020 Medonic MSeries activity records for all maintenance, reagent logs, calibrations, QC and patient testing from TP#2. TP#2 confirmed that the laboratory did not record and retain any manual logs, other than what was held in the analyzer which indicated any activity with maintenance and reagent lot number/expiration dates. TP#2 unsuccessfully attempted to locate the requested information from 10/31/2019 to 01/21/2020 on the analyzer and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/21/2020 at 12:15 PM.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
 CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
 Based on record review and an interview with the Laboratory Director, the laboratory failed to establish and follow written policies and procedures to assess the competency of testing personnel (TP). All patient Endocrinology, Immunology and Hematology testing performed in this laboratory from 10/31/2019 to 01/21/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any instructions for assessing the competency of TP. 2. Review of the laboratory's Form CMS-209, approved, signed and dated by the Laboratory Director on 01/20/2020 and provided on the date of the inspection, revealed two TP including the Laboratory Director. 3. The Inspector requested the laboratory's competency assessment policy and procedure and all competency assessment documentation for TP#2 from the Laboratory Director. The Laboratory Director confirmed that the laboratory did not establish a competency assessment policy and procedure, TP#2 was not assessed for competency on the moderately complex Endocrinology, Immunology and Hematology testing performed from 10/31/2019 to 01/21/2020 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/21/2020 at 9:42 AM.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

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.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Laboratory Director, the laboratory failed to have written policies and procedures available to the laboratory personnel for the thyroid stimulating hormone (TSH), Vitamin D (VitD), Immunoglobulin E (IgE) and complete blood count (CBC) with five part automated differential (auto diff) testing procedures. All patient testing performed in this laboratory from 10/31/2019 to 01/21/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure packet titled "Ibrahim S Elsheikh MD, Inc Laboratory Manual", provided on the date of the inspection, found it to be comprised of 12, one-sided pages that included general information of all specimen collection, labeling, handling, processing and send out protocols, all nine waived tests performed as well as the mention of the moderately complex TSH, VitD, IgE, and CBC with auto diff testing procedures performed. 2. Further review of the laboratory's policy and procedure packet revealed the following example of one out of four of the moderately complex testing protocols in total: "IgE allergy Test (Hitachi) - See manufacturer procedural manual Venous sample is obtained from the patient. Then specimen is centrifuged for 10 minutes to separate serum. Procedural manual is followed to analyze patient's sample. Prior to run patient's sample, control is run first. Quality assurance measure Control is run prior to testing patients' samples. Result of control must be within acceptable parameter before analyzing patients' data. See procedural manual. Proficiency Testing Hitachi Reference Lab" 3. The Inspector requested the laboratory's TSH, VitD, IgE and CBC with auto diff testing policies and procedures from the Laboratory Director. The Laboratory Director confirmed the packet provided was the laboratory's only written policies and procedures and referenced the manufacturer's manual as needed and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01 /21/2020 at 9:25 AM.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test 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 Director, the laboratory failed to include in a policy and procedure for thyroid stimulating hormone (TSH), Vitamin D (VitD), Immunoglobulin E (IgE) and complete blood count (CBC) with five part automated differential (auto diff) testing procedures the requirements for patient preparation, specific specimen requirements, storage, preservation, transportation, criteria for specimen acceptability and rejection, step-by-step performance of the procedure (including interpretation of results), preparation of calibrators, controls, reagents and other materials used in testing, calibration and calibration verification procedures, the reportable range of test results for the test system, control procedures, corrective actions to take when calibration results fail to meet the laboratory's criteria for acceptability, limitations and interfering substances of the test system, the laboratory's established or verified reference ranges, life-threatening, panic or alert test results and the laboratory's system for entering results in the patient record and reporting patient results. All patient testing performed in this laboratory from 10/31/2019 to 01/21/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure packet titled "Ibrahim S Elsheikh MD, Inc Laboratory Manual", provided on the date of the inspection, found it to be comprised of 12, one-sided pages that included general specimen collection, labeling, handling, processing and send out protocols, all nine waived tests performed as well as a mention of the moderately complex TSH, VitD, IgE and CBC with auto diff testing procedures performed. 2. Further review of the laboratory's policy and procedure packet revealed the following example of two out of four of the moderately complex testing protocols in total: "TSH, Vitamin D (FastPack IP) Venous sample is obtained from the patient. Then specimen is centrifuged for 10 minutes to separate serum. Procedural manual and instrument instruction are followed to analyze sample. Results are scanned in patients' charts. Quality assurance measure Please refer to the QA manual (available in the lab) Proficiency Testing Wisconsin State Laboratory of Hygiene (WSLH) program" 3. The Inspector requested the laboratory's TSH, VitD, IgE and CBC with auto diff testing policies and procedures with all of the required components for each test system from the Laboratory Director. The Laboratory Director confirmed the packet provided was the laboratory's only written policy and procedure, the testing personnel referred to the manufacturer's manuals as needed and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/21/2020 at 9:25 AM.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

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 record review and an interview with the Laboratory Director, the Laboratory Director failed to ensure that policies and procedures were approved, signed and dated

before use. All patient testing procedures in this laboratory from 10/31/2019 to 01/21/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure packet titled "Ibrahim S Elsheikh MD, Inc Laboratory Manual", provided on the date of the inspection, did not find the Laboratory Director's approval via signature and date, found it to be comprised of 12 one-sided pages and revealed the following typed statements: "Revised January 14, 2020 By Ibrahim S Elsheikh, M.D. Lab director" "...Procedures and changes must be reviewed, approved, and signed by the Lab director prior to use..." 2. The Laboratory Director confirmed the laboratory's established policy and procedure packet did not include the Laboratory Director's approval via signature and date. The interview occurred on 01/21/2020 at 9:25 AM.

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 record review and an interview with testing personnel (TP) #2, the laboratory failed to define criteria consistent with the manufacturer's instructions and document room and refrigerator temperatures and humidity conditions for reliable Immunoglobulin E (IgE) testing procedures. All IgE testing procedures performed in this laboratory from 11/19/2019 to 01/21/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure packet titled "Ibrahim S Elsheikh MD, Inc Laboratory Manual", provided on the date of the inspection, found it to be comprised of 12, one-sided pages and did not find any instructions to monitor and document room and refrigerator temperatures and humidity conditions. 2. Review of the manufacturer's instructions for the Hitachi CLA-1/Optigen Luminometer Immunology analyzer revealed the following: "Specifications... 8.2 Environmental Ambient temperature: 18C to 33C Ambient humidity: 20 to 85 % non-condensing" 3. The Inspector requested the laboratory's policy and procedure for the room and refrigerator temperatures and humidity criteria consistent with the manufacturer's instructions and all temperature and humidity documentation from 11/19/2019 to 01/21/2020 from TP#2. TP#2 confirmed the laboratory did not establish a policy and procedure to monitor and document room and refrigerator temperatures and humidity consistent with the manufacturer's instructions for IgE testing procedures, did not monitor and document room and refrigerator temperatures and humidity from 11/19/2019 to 01/21/2020 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/21/2020 at 12:25 PM.

D5415

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and

when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on direct observation of the Hematology quality control (QC) vials and an interview with testing personnel (TP) #2, the laboratory failed to label the only set of three complete blood count (CBC) with five part automated differential (auto diff) QC vials with the opened date and the opened expiration date. All patient CBC and auto diff testing procedures from 10/31/2019 to 01/21/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Direct observation of the Hematology testing area on 01/21/2020 at 12:40 PM, found one set of three levels of QC vials utilized for CBC with auto diff QC procedures without any indication of the open dates and the opened expiration dates. 2. Review of the "Medonic MSeries User's Manual, Section 6: Quality Control (QC) and Blood Control Memory", revealed the following statement: "Never use an open via longer than recommended by the manufacturer..." 3. TP#2 stated that the hematology Boule QC vials expire 15 days after opening. TP#2 confirmed that the laboratory's only set of three CBC with auto diff QC vials did not have any indication of the opened dates, could not confirm the opened expiration dates and was unable to verify that they were acceptable to use. The interview occurred on 01/21/2020 at 12:40 PM.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Laboratory Director, the laboratory failed to demonstrate performance specifications as established by the manufacturer for accuracy, precision, reportable range and reference intervals prior to reporting patient test results on the newly installed Medonic MSeries Hematology analyzer on 10/31/2019, the newly installed Qualigen FastPack Endocrinology analyzer on 11/19/2019 and the newly installed Hitachi CLA-1/Optigen Luminometer Immunology analyzer on 11/19/2019. All complete blood count (CBC) with five part automated differential (auto diff), thyroid stimulating hormone (TSH), Vitamin D (VitD) and Immunoglobulin E (IgE) testing procedures performed in this laboratory from 10/31/2019 to 01/21/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure packet titled "Ibrahim S Elsheikh MD, Inc Laboratory Manual", provided on the date of the inspection, did not find any instructions for the laboratory to verify the manufacturer's performance specifications to include accuracy, precision, reportable ranges and reference ranges for the Medonic MSeries Hematology analyzer, the Qualigen FastPack Endocrinology analyzer and the Hitachi CLA-1/Optigen Luminometer Immunology analyzer prior to testing and reporting patient specimens, 2. Review of

the installation documentation for the Medonic MSeries Hematology analyzer, the Qualigen FastPack Endocrinology analyzer and the Hitachi CLA-1/Optigen Luminometer Immunology analyzer revealed each vendor completed their respective installation checklists and testing personnel training checklists. 3. The Inspector requested the laboratory's performance specification documentation activities that were approved, signed and dated by the Laboratory Director prior to patient testing for the newly installed Medonic MSeries Hematology analyzer, the Qualigen FastPack Endocrinology analyzer and the Hitachi CLA-1/Optigen Luminometer Immunology analyzer from the Laboratory Director. The Laboratory Director confirmed that the vendor completed their respective installation checklists that included accuracy, precision, reportable range and reference ranges activities, the laboratory did not conduct any performance verification activities, the laboratory only calibrated and ran quality controls prior to patient testing and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/21/2020 at 10:45 AM.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on record review and an interview with testing personnel (TP) #2, the laboratory failed to establish, perform and document a maintenance protocol that ensured accurate and reliable testing performance which was necessary for thyroid stimulating hormone (TSH), Vitamin D (VitD), Immunoglobulin E (IgE) and complete blood count (CBC) with five part automated differential (auto diff) test results and test result reporting. All TSH, VitD, IgE and CBC with auto diff testing performed in this laboratory from 10/31/2019 to 01/21/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure packet titled "Ibrahim S Elsheikh MD, Inc Laboratory Manual", provided on the date of the inspection, did not find any mention of any maintenance policies and procedures. 2. Direct observation of the laboratory work area, on 01/21/2020 at 12:17 PM, did not find any evidence of manual maintenance logs or any records for the Medonic MSeries Hematology analyzer, the Qualigen FastPack Endocrinology analyzer and the Hitachi CLA-1/Optigen Luminometer Immunology analyzer. TP#2 stated the Medonic MSeries Hematology analyzer held the required instrument maintenance records on board. 3. The Inspector requested the laboratory's maintenance policy and procedure and all Medonic MSeries Hematology analyzer, Qualigen FastPack Endocrinology analyzer and Hitachi CLA-1/Optigen Luminometer Immunology analyzer maintenance documentation from 10/31/2019 to 01/21/2020 from TP#2. TP#2 stated the Medonic MSeries maintenance records were kept on-board, but was not able to retrieve any records from 10/31/2019 to 12/28/2019. TP#2 confirmed that the laboratory did not establish an instrument maintenance policy and procedure, did not perform and document any Qualigen FastPack Endocrinology analyzer and the Hitachi CLA-1/Optigen Luminometer Immunology analyzer

maintenance activities from 10/31/2019 to 01/21/2020 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/21/2020 at 12:17 PM.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Laboratory Director, the laboratory failed to perform and document complete blood count (CBC) with five part automated differential (auto diff) quality control (QC) testing procedures each day of patient testing. CBC with auto diff testing on 10 out of 10 patient samples tested and reported on 12/28/2019 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure packet titled "Ibrahim S Elsheikh MD, Inc Laboratory Manual", provided on the date of the inspection, found the following statement: "Controls are run daily prior to analyzing patients' samples." 2. Direct observation of the laboratory's Medonic MSeries onboard CBC and auto diff QC records, on 01/21/2020 at 12:50 PM, revealed documentation, on 12/28/2019, that there were three auto background checks, a normal QC, three un-identified sample attempts and 10 patients' tested on the Medonic MSeries analyzer for CBC with auto diff QC testing as listed below: 12/28/20019 Sequence Time of Number Testing 489 1034 Auto background 490 1043 Auto background 491 1052 Auto background 492 1110 Patient sample 493 1112 Un-identified sample 494 1126 2190902+ (normal QC) 495 1128 Un-identified sample 496 1129 Un-identified sample 497 1136 Patient sample 498 1156 Patient sample 499 1213 Patient sample 500 1235 Patient sample 501 1305 Patient sample 502 1306 Patient sample 503 1325 Patient sample 504 1326 Patient sample 505 1417 Patient sample 3. TP#2 confirmed there was one patient CBC with auto diff sample tested and reported without any QC performed, the low and high QC testing was not identified and was not confirmed to have been successfully performed. Nine other patient samples had CBC with auto diff testing performed and results reported. TP#2 further confirmed that the onboard QC and patient documentation prior to 12/27/2019 at 1:29 PM was not retrievable. The interview occurred on 01/21/2020 at 12:50 PM.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
 Based on record review and interviews with the Laboratory Director and testing personnel (TP) #2, the laboratory failed to document any corrective actions taken when the complete blood count (CBC) with five part automated differential (auto diff) testing procedures performed outside of established operating parameters. All patient CBC with auto diff testing performed on 12/28/2019, 10 out of 10, had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure packet titled "Ibrahim S Elsheikh MD, Inc Laboratory Manual", provided on the date of the inspection, did not find any instructions to document errors and incidents along with the actions taken to correct the problem(s) identified. 2. Review of the laboratory's Medonic MSeries quality control (QC) records did not find any documented corrective action when two out of three of the background checks were not acceptable as identified on 12/28/2019 and listed below: 12/28/2019 Sequence Time of Instrument printout Number Testing 489 1034 Auto background DP 490 1043 Auto background DP 491 1052 Auto background DP; diluent system problem 3. The Inspector requested the laboratory's approved corrective action policy and procedure and all corrective action documentation from 10/31/2019 to 01/21/2020 from the Laboratory Director and TP#2. The Laboratory Director and TP#2 confirmed the laboratory did not have an established corrective action policy and procedure, did not document errors or incidents along with the corrective action measures taken and was unable to provide the requested documentation on the date of the inspection. The interviews occurred on 01/21/2020 at 12:50 PM.

D5805

TEST REPORT
 CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
 Item 1: Based on record review and an interview with the Laboratory Director, the laboratory failed to include positive patient identification (ID) for the thyroid stimulating hormone (TSH), Vitamin D (VitD), Immunoglobulin E (IgE) and complete blood count (CBC) with five part automated differential (auto diff) testing procedures on the final instrument printout test report. All patient TSH, VitD, IgE and CBC with auto diff testing procedures performed from 10/31/2019 to 01/21/2020 were affected by this deficient practice. Findings Include: 1. Review of 11 out of 11 TSH and 16 out of 16 VitD test instrument printouts that were scanned into the patient's EMR as well as manually entered into the final EMR test reports did not find positive patient ID on the EMR scanned instrument printout as indicated below: Scanned TSH Scanned VitD Instrument Instrument Printout Printout 11 of 11 16 of 16 only first name or only first/last name 2. Review of nine out of nine of the laboratory's corresponding IgE allergy testing instrument printouts, scanned final test reports and EMR final test reports did not find positive patient ID as indicated below: IgE Scanned IgE Instrument Worksheet as Printout Final IgE Test Report 9 of 9 9 of 9 no only first name patient or ID only first/last name 3. Review of 36 out of 36 of the

laboratory's corresponding CBC with auto diff scanned final test reports and EMR final test reports did not find positive patient ID as indicated below: Scanned Instrument EMR Final Printout as Final Test Report CBC/auto diff Test Report 36 out of 36 36 out of 36 only first name or no CBC/auto diff first/last name results. Refers to scanned instrument printout 4. The Laboratory Director confirmed that the laboratory failed to indicate positive patient identification on the scanned instrument printouts as the final TSH, VitD, IgE and CBC with auto diff test reports. The interview occurred on 01/21/2020 at 11:05 AM. Item 2: Based on record review and an interview with the Laboratory Director, the laboratory failed to include on the final instrument printout report the name and address of the laboratory location where the Immunoglobulin E (IgE) and complete blood count (CBC) with five part automated differential (auto diff) testing procedures, as well as where all testing performed at other laboratories, were performed. All patient IgE, CBC with auto diff and outside laboratory testing procedures performed from 10/31/2019 to 01/21/2020 were affected by this deficient practice. Findings Include: 1. Review of nine out of nine IgE and 36 out of 36 CBC with auto diff final instrument test reports, revealed the name and address of the laboratory location where the testing was performed was not indicated. 2. Review of 5 out of 5 of the laboratory's final EMR test reports did not indicate the name and address of the laboratory location where the reported reference laboratory testing was performed. 3. The Laboratory Director confirmed that the laboratory failed to indicate on the final test report the name and address of the laboratory location where the IgE, CBC with auto diff and reference laboratory testing procedures were performed. The interview occurred on 01/21/2020 at 11:05 AM. Item 3: Based on record review and an interview with the Laboratory Director, the laboratory failed to include the Immunoglobulin E (IgE) and complete blood count (CBC) with five part automated differential (auto diff) test results on the electronic medical record (EMR) final test report. All patient IgE and CBC with auto diff testing procedures performed from 10/31/2019 to 01/21/2020 were affected by this deficient practice. Findings Include: 1. Review of nine out of nine of the laboratory's corresponding IgE scanned final test reports and EMR final test reports did not find the patient's IgE test results on the EMR final test report as indicated below: EMR Final Test Report 9 out of 9; no IgE results. (Refers to the scanned worksheet that has the instrument printout taped to it) 2. Review of 36 out of 36 of the laboratory's CBC with auto diff scanned final test reports and EMR final test reports did not find the patient's CBC with auto diff test results on the EMR final test report as indicated below: EMR Final Test Report 36 out of 36; no CBC/auto diff results. (Refers to the scanned instrument printout) 3. The Laboratory Director confirmed that the laboratory failed to include the patient's IgE and CBC with auto diff test results on the EMR final test report. The interview occurred on 01/21/2020 at 11:05 AM.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:
Based on record review and an interview with the Laboratory Director and testing personnel (TP) #2, the Laboratory Director failed to provide overall management and direction in accordance with 493.1407 of this subpart for the specialties; Immunology, Endocrinology and Hematology. All patient thyroid stimulating hormone (TSH),

Vitamin D (VitD), Immunoglobulin E (IgE) and complete blood count (CBC) with five part automated differential (auto diff) testing procedures performed in this laboratory from 10/31/2019 to 01/21/2020 had the potential to be affected by this deficient practice. Findings Include: 1. The Laboratory Director failed to ensure that the Immunology, Endocrinology and Hematology testing systems used in the laboratory provided quality laboratory services in the analytic and postanalytic phases of testing. (Refer to D6007) 2. The Laboratory Director failed to ensure the laboratory's quality assessment program was established and maintained to assure the quality of the TSH, VitD, IgE and CBC with auto diff testing procedures performed. (Refer to D6021) 3. The Laboratory Director failed to ensure that TP#2 had demonstrated that they could perform TSH, VitD, IgE and CBC with auto diff testing procedures reliably to provide and report accurate results prior to performing patient tests. (Refer to D6029) 4. The Laboratory Director failed to ensure that policies and procedures were established for monitoring individuals who conducted preanalytical, analytical, and postanalytical phases of testing. (Refer to D 6030)

D6007

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:
Based on record review and an interview with the Laboratory Director, the Laboratory Director failed to ensure that the Endocrinology, Immunology and Hematology testing systems used in the laboratory provided quality laboratory services in the analytic and postanalytic phases of testing. All patient thyroid stimulating hormone (TSH), Vitamin D (VitD), Immunoglobulin E (IgE) and complete blood count (CBC) with five part automated differential (auto diff) testing procedures performed from 10/31/2019 to 01/21/2020 had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to have written policies and procedures available to the laboratory personnel for the TSH, VitD, IgE and CBC with auto diff testing procedures. (Refer to D5401) 2. The laboratory failed to include in a policy and procedure for TSH, VitD, IgE and CBC with auto diff testing procedures the requirements for patient preparation, specific specimen requirements, storage, preservation, transportation, criteria for specimen acceptability and rejection, step-by-step performance of the procedure (including interpretation of results), preparation of calibrators, controls, reagents and other materials used in testing, calibration and calibration verification procedures, the reportable range of test results for the test system, control procedures, corrective actions to take when calibration results fail to meet the laboratory's criteria for acceptability, limitations and interfering substances of the test system, the laboratory's established or verified reference ranges, life-threatening, panic or alert test results, the laboratory's system for entering results in the patient record and reporting patient results. (Refer to D5403) 3. The Laboratory Director failed to ensure that policies and procedures were approved, signed and dated before use. (Refer to D5407) 4. The laboratory failed to define criteria consistent with

the manufacturer's instructions and document room and refrigerator temperatures and humidity conditions for reliable TSH, VitD, IgE and CBC with auto diff testing procedures. (Refer to D5413) 5. The laboratory failed to label the only set of three CBC with auto diff quality control (QC) vials with the opened date and the opened expiration date. (Refer to D5415) 6. The laboratory failed to demonstrate performance specifications as established by the manufacturer for accuracy, precision, reportable range and reference intervals prior to reporting patient test results on the newly installed Medonic MSeries Hematology analyzer on 10/31/2019, the newly installed Qualigen FastPack Endocrinology analyzer on 11/19/2019 and the newly installed Hitachi CLA-1/Optigen Luminometer Immunology analyzer on 11/19/2019. (Refer to D5421) 7. The laboratory failed to establish, perform and document a maintenance protocol that ensured accurate and reliable testing performance which was necessary for TSH, VitD, IgE and CBC with auto diff test results and test result reporting. (Refer to D5433) 8. The laboratory failed to perform and document CBC with auto diff QC testing procedures each day of patient testing. (Refer to D5481) 9. The laboratory failed to document any corrective actions taken when the CBC with auto diff testing procedures performed outside of established operating parameters. (Refer to D5781) 10. The laboratory failed to include positive patient identification (ID) for the TSH, VitD, IgE and CBC with auto diff testing procedures and the IgE and CBC with auto diff test results on the final test reports. (Refer to D5805, Item 1, Item 2 and Item 3)

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on record review and an interview with the Laboratory Director, the Laboratory Director failed to ensure the laboratory's quality assessment program was established and maintained to assure the quality of the thyroid stimulating hormone (TSH), Vitamin D (VitD), Immunoglobulin E (IgE) and complete blood count (CBC) with five part automated differential (auto diff) testing procedures performed. All patient TSH, VitD, IgE and CBC with auto diff testing performed from 10/31/2019 to 01/21/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure packet titled "Ibrahim S Elsheikh MD, Inc Laboratory Manual", provided on the date of the inspection, found it to be comprised of 12, one-sided pages that included general information of all specimen collection, labeling, handling, processing and send out protocols, all nine waived tests performed as well as the mention of the moderately complex TSH, VitD, IgE and CBC with auto diff testing performed. 2. Further review of the laboratory's policy and procedure packet did not find any mention of the laboratory's quality assessment program. 3. The Inspector requested the laboratory's quality assessment policy and procedure and all quality assessment documentation from 10/31/2019 to 01/21/2020 from the Laboratory Director. The Laboratory Director confirmed that the laboratory did not establish a quality assessment policy and procedure, did not conduct and document quality assessment activities and was unable to provide the requested

documentation on the date of the inspection. The interview occurred on 01/21/2020 at 9:42 AM.

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:

Based on record review and an interview with the Laboratory Director, the Laboratory Director failed to ensure that testing personnel (TP) #2 had demonstrated that they could perform thyroid stimulating hormone (TSH), Vitamin D (VitD), Immunoglobulin E (IgE) and complete blood count (CBC) with five part automated differential (auto diff) testing procedures reliably to provide and report accurate results prior to performing patient testing. All patient TSH, VitD, IgE and CBC with auto diff testing performed by TP#2 from 10/31/2019 to 01/21/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any instructions for assessing the competency of testing personnel (TP). 2. The Inspector requested the laboratory's competency assessment policy and procedure and all competency assessment documentation for TP#2 from the Laboratory Director. The Laboratory Director confirmed that the laboratory did not establish a competency assessment policy and procedure, TP#2 did not demonstrate that they could perform the moderately complex Endocrinology, Immunology and Hematology testing procedures reliably to provide and report accurate results prior to patient testing and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/21/2020 at 9:42 AM.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Laboratory Director, the Laboratory

Director failed to ensure that policies and procedures were established for monitoring individuals who conducted preanalytical, analytical, and postanalytical phases of testing. All patient thyroid stimulating hormone (TSH), Vitamin D (VitD), Immunoglobulin E (IgE) and complete blood count (CBC) with five part automated differential (auto diff) testing procedures performed from 10/31/2019 to 01/21/2020 had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to establish and follow written policies and procedures to assess the competency of testing personnel. (Refer to D5209)