

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1053649	(X3) Date Survey Completed 11/17/2021
Name of Provider or Supplier Riad R Hajjar Md, Pc	Street Address, City, State 1201 Stone Street Suite 5, Port Huron, MI	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: . Based on review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS approved proficiency testing program for the chemistry analyte: carbon dioxide (CO2). Findings include: Review of the CMS database and the API proficiency testing reports showed unsatisfactory performance for 2 of 3 proficiency testing events. Refer to 2096</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p>

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

. Based on review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, the laboratory failed to achieve satisfactory performance for the chemistry analyte: carbon dioxide (CO₂) for 2 of 3 consecutive testing events. Findings include: Unsatisfactory performance for 2 of 3 consecutive proficiency testing events constitutes unsuccessful performance for CO₂. CO₂ PT event Score 1st event 2021 40% 3rd event 2021 0%

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 observation, record review, and interview with Testing Personnel (TP) #1, the laboratory failed to retain the chemistry Mindray BS 200 quality control documents for 2 (11/17/2019 to 11/17/2021) of 2 years. Findings include: 1. The surveyor observed while reviewing chemistry and endocrinology quality control records a break from 9/16/2020 to 2/04/2021 in the records. 2. When queried on 11/17/2021 at 12:14 pm, TP1 stated that she had deleted the files on 2/18/2021. 3. A record review for 1 (#492) of 13 patient final reports tested on 12/16/2020 revealed the laboratory did not have any documentation of the quality control records for that testing date. 4. An interview on 11/17/2021 at 12:14 pm, TP1 confirmed the quality control records were not maintained for 2 years.

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 interview, the laboratory failed to ensure written competency policies were implemented for 2 (Clinical Consultant and the Technical Consultant) of 2 non-testing technical personnel based on the federal regulatory responsibilities. Findings include: 1. A record review of the CMS-209 revealed for 2 of 2 non-testing technical positions, the laboratory did not implement the federal regulatory responsibilities competency assessment for 2020 and 2021. 2. An interview on 11/17/2021 at 9:15 am, Testing Personnel #1 confirmed the lab did not implement competency assessments in 2020 and 2021.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

. Based on record review, lack of documentation, and interview with Testing Personnel (TP) #1, the laboratory failed to verify the accuracy of the chemistry and endocrinology testing at least twice annually for 3 (2nd of 2020 and 1st and 2nd of 2021) of 5 testing events in 2 years. Findings include: 1. A record review of the twice a year verification of accuracy (linearity) documents revealed for 3 of 5 events in 2 years a lack of documentation of the process being performed and documented for the following analytes: a. chemistry analytes: sodium, potassium, chloride, carbon dioxide, albumin, alkaline phosphatase, aspartate transamine, alanine transaminase, total bilirubin, calcium, creatinine, glucose, total protein, and urea nitrogen b. endocrinology analytes: vitamin D, thyroid stimulating hormone, and free thyroxine 2. An interview on 11/17/2021 at 10:31 am, TP1 confirmed there was no verification of accuracy performed or documented for 3 of 5 events.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

. Based on record review, lack of documentation, and interview with Testing Personnel (TP) #1, the laboratory failed to 1) monitor and evaluate the monthly quality assurance for 20 (4/2020 to 11/2021) of 24 months and 2) monitor and evaluate the pre-analytic, analytic, and post analytic systems quarterly for 6 (2nd-4th quarters 2020 and 1st-3rd quarters in 2021) of 6 quarters. Findings include: 1. A record review revealed a lack of documentation for the monthly quality assurance reviews for 20 (4/2020 to 11/2021) of 24 months reviewed. 2. A record review revealed a lack of documentation for the quarterly quality assurance reviews for 6 (2nd-4th quarters 2020 and 1st-3rd quarters in 2021) of 6 quarters. 3. An interview on 11/17/2021 at 1:00 pm, TP1 confirmed the monthly and quarterly quality assurance checks were not performed and documented.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt

from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel (TP) #1, the laboratory failed to perform and document the chemistry low-density lipoprotein (LDL) instrument calculated check for accuracy periodically for 2 (2020 and 2021) of 2 years reviewed. Findings include: 1. A record review of the LDL calculations revealed for 2 (2020 and 2021) of 2 years a lack of documentation of the periodic check on the instrument calculation. 2. An interview on 11/17/2021 at 9:56 am, TP1 confirmed the calculations were not checked in 2020 and 2021.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

. Based on lack of documentation and interview with the Testing Personnel (TP) #1, the Technical Consultant (TC) failed to evaluate the annual competency for 1 (TP1) of 1 TP performing the moderately complex chemistry and hematology testing in 2021. Findings include: 1. A record review of the competency evaluations revealed a lack of documentation for the annual competency for 1 (TP1) of 1 TP performing the moderately complex chemistry and hematology testing. 2. When queried on 11/17/2021 at 9:16 am, TP1 was not able to provide the surveyor the documents requested for competency assessments. 3. An interview on 11/17/2021 9:16 am, TP1 confirmed the annual competency assessments had not been performed and documented in 2021.