

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0482101	(X3) Date Survey Completed 05/04/2023
Name of Provider or Supplier Paris Family Physicians Pa	Street Address, City, State 1128 Clarksville Street Suite 100, Paris, TX	
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	An onsite survey conducted 5/4/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory policy, laboratory proficiency testing (PT) records, and confirmed in interview, the laboratory failed to test PT samples in the same number of times that it routinely tests patients for 13 of 40 PT Chemistry Core and Hematology samples, that had critical results, reviewed from 2021 to 2023. The findings included: 1. Review of the laboratory policy including laboratory set panic values had the following instruction: "The following listing will provide a laboratory guideline to address any patient values "low" or "high" that indicate a call for immediate attention. Good laboratory practice dictates the repeat testing of such values, if possible. Any values verified as critical will be relayed to the physician or nurse, as soon as possible. Panic Values Test Low Limit High Limit Hgb 8 gms/dL 20 gms/dL Hct 24% 60% Plt 30 K/uL 800 K/uL WBC 2 K/uL 20 K/uL Glucose 40mg /dL 400 mg/dL Na 115 mmol/L 160 mmol/L K+ 2.5 mmol/L 5.8 mmol/L Cl 75 mmol /L 135 mmol/L CO2 10 mmol/L 40 mmol/L Ca 6 mg/dL 12 mg/dL 2. Review of the laboratory proficiency testing records for 2022 and 2023 had the following events for the Chemistry Core and Hematology/Coagulation specialties with no documentation of repeat testing to confirm critical results. 2022: Chemistry Core 1st Event Sample CH-01 Analyte - Result Na+ - 125 mmol/L Sample CH-02 Analyte - Result Ca - 12.8 mg/dL K - 7.6 mmol/L Na+ - 170 mmol/L Sample CH-03 Analyte - Result Ca - 5.2 mg/dL CO2 - 5 mmol/L Sample CH-04 Analyte - Result K - 5.8 mmol/L Chemistry Core 3rd Event Sample CH-14 Analyte - Result Ca - 12.7 mg/dL K - 6.9 mmol/L Na+</p>

- 161 mmol/L Sample CH-15 Analyte - Result K - 5.9 mmol/L Hematology /Coagulation 2nd Event Sample HSY-06 Analyte - Result Hct - 16% Hgb - 6.0 g/dL Hematology/Coagulation 3rd Event Sample HSY-13 Analyte - Result Hct - 16% Hgb - 5.9 g/dL 2023: Hematology / Coagulation 1st Event Sample HSY-04 Analyte - Result Hgb - 6.1 gms/dL Hct - 17 % Chemistry Core 1st Event Sample CH-01 Analyte - Result Calcium 6.0 mg/dL Sample CH-03 Analyte - Result Calcium - 13.4 mg/dL CO2 - 40 mmol/L K - 7.4 mmol/L Na+ - 177 mmol/L Sample CH-04 Analyte - Result Na+ - 142 mmol/L Sample CH-05 K - 5.9 mmol/L Na+ - 162 mmol/L 3. In an interview on 5/4/2023 at 12:10 hours, in the conference room, testing person (TP) 1 confirmed that the critical results for the above proficiency testing samples had not been rerun to confirm the critical result as they do patients. Key: Ca - Calcium Cl- Chloride CO2 - Carbon dioxide g/dL - grams per deciliter gms/dL - grams per deciliter Hgb - Hemoglobin Hct - Hematocrit K - Potassium K/uL - thousands per microliter mg/dL - milligram per deciliter mmol/L - millimole per liter Na+ - Sodium Plt - platelet WBC - White blood cell

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of laboratory quality control (QC) documents, QC instructions for use, laboratory documents, patient reports, and confirmed in interview, the laboratory failed to have a control procedure in place to detect immediate errors for five of five random analytes reviewed (Cholesterol, Glucose, Chloride, Carbon Dioxide, total Bilirubin) from January to March 2023 on the Ortho VITROS 350 Chemistry analyzer. The findings included : 1. Review of the laboratory policy titled "Quality Control Policy" section "Acceptable Limits" had the following statement: "A. Manufacturer's acceptable ranges will be followed until enough data is generated to establish new means for Chemistry and Special Chemistry analytes. This is usually a month of data or 20 data points." Surveyor queried, on 5/4/2023 at 13:45 how the laboratory set its standard deviation (SD) for new QC lots. Testing person (TP) 1 stated that the laboratory used the 2SD from the performance verifiers (PV) package insert with each new lot of quality control. Surveyor queried if the QC results were determined acceptable through the laboratory information system (LIS) or from the Otho Vitros 350 Chemistry analyzer and TP1 stated the laboratory accepted QC through the LIS. 2. A review of QC documents from January to March 2023, of 5 random analytes (Cholesterol, Glucose, Chloride, Carbon Dioxide, total Bilirubin) that were tested on the Ortho Vitros 350 chemistry analyzer had the following 2SD acceptability criteria in the laboratory information system (LIS) that did not meet the 2SD acceptability criteria as established by the performance verifiers. Control 1, Lot F9070, Exp 11/8/2023: Cholesterol: Mean - 144.945 mg/dL LIS Expected 2SD

Range: 131.9 - 157.99 mg/dL PV Expected 2SD Range: 140.615 - 149.275 mg/dL
Glucose: Mean 87 mg/dL LIS Expected 2SD Range: 79.5 - 94.5 mg/dL PV Expected
2SD Range: 84.92 - 89.08 mg/dL Chloride: Mean 77.9 mmol/L LIS Expected 2SD
Range: 73.9 - 81.9 mmol/L PV Expected 2SD Range: 76.8 - 79.0 mmol/L Carbon
Dioxide: Mean 28.1 mmol/L LIS Expected 2SD Range: 25.1 - 31.1 mmol/L PV
Expected 2SD Range: 26.8 - 29.4 mmol/L Total Bilirubin: Mean 1.56 mg/dL LIS
Expected 2SD Range: 1.24 - 1.88 mg/dL PV Expected 2SD Range: 1.48 - 1.64 mg/dL
Control 2, Lot G9072, Exp 11/8/2023: Cholesterol: Mean 242 mg/dL LIS Expected
2SD Range: 227 - 257 mg/dL PV Expected 2SD Range: 236.01 - 247.99 mg/dL
Glucose: Mean 293.7 mg/dL LIS Expected 2SD Range: 276.2 - 311.2 mg/dL PV
Expected 2SD Range: 288.98 - 298.42 mg/dL Chloride: Mean 106 mmol/L LIS
Expected 2SD Range: 102 - 110 mmol/L PV Expected 2SD Range: 104.6 - 107.4
mmol/L Carbon Dioxide: Mean 15.9 mmol/L LIS Expected 2SD Range: 11.9 - 19.9
mmol/L PV Expected 2SD Range: 14.9 - 16.9 mmol/L Total Bilirubin: Mean 15.25
mg/dL LIS Expected 2SD Range: 13.95 - 16.55 mg/dL PV Expected 2SD Range:
14.79 - 15.71 mg/dL 3. Review of laboratory QC records for January to March 2023
had the following days where QC was outside of the PV Expected 2SD range that the
laboratory was to use as acceptability criteria. Control 1, Lot F9070, Exp 11/8/2023
Cholesterol: Mean - 144.945 mg/dL PV Expected 2SD Range: 140.615 - 149.275 mg
/dL January 2023: 1/3/2023 - 152 mg/dL 1/4/2023 - 152 mg/dL 1/5/2023 - 155 mg/dL
1/9/2023 - 156 mg/dL 1/10/2023 - 156 mg/dL 1/11/2023 - 134 mg/dL 1/12/2023 - 150
mg/dL 1/16/2023 - 157 mg/dL 1/17/2023 - 150 mg/dL 1/18/2023 - 158 mg/dL 1/19
/2023 - 150 mg/dL 1/26/2023 - 154 mg/dL 1/30/2023 - 152 mg/dL February 2023: 2/6
/2023 - 150 mg/dL 2/16/2023 - 150 mg/dL 2/20/2023 - 150 mg/dL 2/23/2023 - 151 mg
/dL 2/27/2023 - 150 mg/dL March 2023: 3/1/2023 - 153 mg/dL 3/2/2023 - 152 mg/dL
3/9/2023 - 150 mg/dL 3/16/2023 - 155 mg/dL 3/20/2023 - 151 mg/dL 3/21/2023 - 153
mg/dL 3/27/2023 - 152 mg/dL Glucose: Mean 87 mg/dL PV Expected 2SD Range:
84.92 - 89.08 mg/dL January 2023: 1/3/2023 - 89.5 mg/dL 1/5/2023 - 91.0 mg/dL 1/9
/2023 - 92.0 mg/dL 1/10/2023 - 93.0 mg/dL 1/11/2023 - 93.0 mg/dL 1/12/2023 - 89.2
mg/dL 1/16/2023 - 91.0 mg/dL 1/17/2023 - 91.0 mg/dL 1/18/2023 - 94.3 mg/dL 1/19
/2023 - 93.0 mg/dL 1/23/2023 - 91.0 mg/dL 1/24/2023 - 90.0 mg/dL 1/25/2023 - 91.0
mg/dL 1/26/2023 - 93.0 mg/dL 1/30/2023 - 92.0 mg/dL February 2023: 2/2/2023 -
90.0 mg/dL 2/8/2023 - 90.0 mg/dL 2/16/2023 - 91.1 mg/dL 2/20/2023 - 91.0 mg/dL 2
/21/2023 - 91.0 mg/dL 2/22/2023 - 91.0 mg/dL 2/23/2023 - 91.0 mg/dL 2/28/2023 -
90.0 mg/dL March 2023: 3/2/2023 - 91.0 mg/dL 3/9/2023 - 91.2 mg/dL 3/16/2023 -
90.7 mg/dL 3/20/2023 - 92.6 mg/dL 3/21/2023 - 94.0 mg/dL Chloride: Mean 77.9
mmol/L PV Expected 2SD Range: 76.8 - 79.0 mmol/L January 2023: 1/3/2023 - 76
mmol/L 1/9/2023 - 80.0 mmol/L 1/10/2023 - 80.0 mmol/L 1/11/2023 - 81.0 mmol/L 1
/19/2023 - 81.0 mmol/L 1/23/2023 - 80.0 mmol/L 1/24/2023 - 80.0 mmol/L 1/25/2023
- 80.0 mmol/L 1/30/2023 - 81.0 mmol/L February 2023: 2/16/2023 - 81 mmol/L 2/20
/2023 - 81 mmol/L 2/21/2023 - 80 mmol/L 2/28/2023 - 80 mmol/L March 2023: 3/1
/2023 - 80 mmol/L 3/2/2023 - 81 mmol/L 3/16/2023 - 81 mmol/L 3/20/2023 - 81
mmol/L 3/21/2023 - 81 mmol/L 3/23/2023 - 80 mmol/L 3/29/2023 - 80 mmol/L
Carbon Dioxide: Mean 28.1 mmol/L PV Expected 2SD Range: 26.8 - 29.4 mmol/L
January 2023: 1/4/2023 - 25.7 mmol/L 1/5/2023 - 26.0 mmol/L 1/9/2023 - 26.0 mmol
/L 1/10/2023 - 26.0 mmol/L 1/11/2023 - 25.1 mmol/L 1/12/2023 - 25.9 mmol/L 1/16
/2023 - 26.5 mmol/L 1/18/2023 - 26.0 mmol/L 1/25/2023 - 26.0 mmol/L 1/30/2023 -
25.7 mmol/L February 2023: 2/6/2023 - 26.0 mmol/L 2/16/2023 - 25.90 mmol/L 2/20
/2023 - 26.0 mmol/L 2/21/2023 - 26.0 mmol/L 2/22/2023 - 26.0 mmol/L 2/23/2023 -
26.0 mmol/L 2/28/2023 - 26.0 mmol/L March 2023: 3/2/2023 - 25.00 mmol/L 3/9
/2023 - 25.80 mmol/L 3/21/2023 - 25.60 mmol/L 3/23/2023 - 25.10 mmol/L 3/30
/2023 - 25.40 mmol/L Total Bilirubin: Mean 1.56 mg/dL PV Expected 2SD Range:
1.48 - 1.64 mg/dL January 2023: 1/3/2023 - 1.8 mg/dL 1/9/2023 - 1.7 mg/dL 1/10

/2023 - 1.7 mg/dL 1/11/2023 - 1.7 mg/dL 1/12/2023 - 1.7 mg/dL 1/17/2023 - 1.7 mg/dL 1/26/2023 - 1.4 mg/dL February 2023: 2/6/2023 - 1.7 mg/dL 2/20/2023 - 1.7 mg/dL 2/27/2023 - 1.7 mg/dL March 2023: 3/7/2023 - 1.7 mg/dL 3/16/2023 - 1.7 mg/dL 3/20/2023 - 1.7 mg/dL 3/28/2023 - 1.4 mg/dL 3/29/2023 - 1.3 mg/dL 3/30/2023 - 1.4 mg/dL Control 2, Lot G9072, Exp 11/8/2023 Cholesterol: Mean 242 mg/dL PV Expected 2SD Range: 236.01 - 247.99 mg/dL January: 1/5/2023 - 249 mg/dL 1/16/2023 - 253 mg/dL 1/24/2023 - 227 mg/dL 1/26/2023 - 232 mg/dL February 2023: 2/23/2023 - 248 mg/dL March 2023: 3/2/2023 - 250 mg/dL 3/20/2023 - 251 mg/dL 3/27/2023 - 251 mg/dL Glucose: Mean 293.7 mg/dL PV Expected 2SD Range: 288.98 - 298.42 mg/dL January 2023: 1/3/2023 - 288.0 mg/dL 1/18/2023 - 300.8 mg/dL 1/19/2023 - 307.0 mg/dL 1/23/2023 - 281.7 mg/dL 1/24/2023 - 286.4 mg/dL February 2023: 2/9/2023 - 302.0 mg/dL 2/16/2023 - 307.2 mg/dL 2/20/2023 - 301.0 mg/dL 2/22/2023 - 303.0 mg/dL 2/27/2023 - 302.0 mg/dL 2/28/2023 - 303.0 mg/dL March 2023: 3/1/2023 - 309.0 mg/dL 3/2/2023 - 306.3 mg/dL 3/7/2023 - 299.4 mg/dL 3/8/2023 - 300.1 mg/dL 3/9/2023 - 304.9 mg/dL 3/13/2023 - 300.4 mg/dL 3/14/2023 - 302.7 mg/dL 3/15/2023 - 306.0 mg/dL 3/20/2023 - 304.6 mg/dL 3/21/2023 - 303.1 mg/dL 3/22/2023 - 301.3 mg/dL 3/27/2023 - 302.6 mg/dL 3/29/2023 - 303.0 mg/dL Chloride: Mean 106 mmol/L PV Expected 2SD Range: 104.6 - 107.4 mmol/L January 2023: 1/3/2023 - 103.0 mmol/L 1/4/2023 - 103.0 mmol/L 1/5/2023 - 104.0 mmol/L 1/9/2023 - 103.0 mmol/L 1/10/2023 - 103.0 mmol/L 1/11/2023 - 104.0 mmol/L 1/23/2023 - 101.0 mmol/L 1/24/2023 - 102.0 mmol/L 1/25/2023 - 103.0 mmol/L 1/26/2023 - 104.0 mmol/L February 2023: 2/6/2023 - 103 mmol/L 2/7/2023 - 104 mmol/L 2/8/2023 - 104 mmol/L 2/16/2023 - 109 mmol/L 2/27/2023 - 104 mmol/L March 2023: 3/1/2023 - 110 mmol/L 3/2/2023 - 108 mmol/L 3/6/2023 - 102 mmol/L 3/13/2023 - 104 mmol/L 3/22/2023 - 108 mmol/L Carbon Dioxide: Mean 15.9 mmol/L PV Expected 2SD Range: 14.9 - 16.9 mmol/L January 2023 1/5/2023 - 14.0 mmol/L 1/10/2023 - 17.10 mmol/L 1/16/2023 - 14.0 mmol/L 1/26/2023 - 14.0 mmol/L 1/30/2023 - 14.0 mmol/L February 2023 2/14/2023 - 17.0 mmol/L 2/16/2023 - 13.3 mmol/L 2/20/2023 - 14.0 mmol/L 2/21/2023 - 14.0 mmol/L March 2023: 3/2/2023 - 12.60 mmol/L 3/7/2023 - 14.60 mmol/L 3/9/2023 - 14.50 mmol/L 3/14/2023 - 13.80 mmol/L 3/15/2023 - 13.50 mmol/L 3/22/2023 - 14.40 mmol/L 3/30/2023 - 14.30 mmol/L Total Bilirubin: Mean 15.25 mg/dL PV Expected 2SD Range: 14.79 - 15.71 mg/dL January 2023 1/5/2023 - 14.4 mg/dL 1/24/2023 - 14.5 mg/dL 1/25/2023 - 14.4 mg/dL 1/26/2023 - 14.4 mg/dL February 2023 2/2/2023 - 14.6 mg/dL 2/9/2023 - 14.6 mg/dL 2/21/2023 - 14.5 mg/dL March 2023 3/7/2023 - 14.7 mg/dL 3/8/2023 - 14.5 mg/dL 3/9/2023 - 14.2 mg/dL 3/27/2023 - 14.7 mg/dL 3/28/2023 - 14.7 mg/dL 3/29/2023 - 14.4 mg/dL 3/30/2023 - 14.6 mg/dL 4. A random review of patients from January to March 2023 had the following 133 patients with testing performed when QC was outside of the PV acceptable 2SD QC range for one or more of the above analytes: January 2023: 1 Patient reviewed 1/10/2023: 1 Patient Patient ID: 5797 February 2023: 56 Patients reviewed 2/2/2023: 6 Patients Patient ID: 18982 5054 31484 9548 34512 5133 2/7/2023: 5 Patients Patient ID: 8633 19873 31385 25125 1797 2/14/2023: 6 Patients Patient ID 20491 33729 21941 5243 8320 21940 2/16/2023: 5 Patients Patient ID: 33019 32506 634 5905 21749 2/20/2023: 6 Patients Patient ID: 24914 32327 34370 3859 13273 34036 2/21/2023: 5 Patients Patient ID: 25352 1748 19618 5729 21009 2/22/2023: 5 Patients Patient ID: 24535 23154 13644 33967 25501 2/23/2023: 5 Patients Patient ID: 30576 6321 34096 15995 11776 2/27/2023: 7 Patients Patient ID: 13816 25904 4031 25045 33177 1461 25038 2/28/2023: 6 Patients Patient ID: 33812 31378 2167 5392 24060 21963 March 2023: 76 Patients reviewed 3/1/2023: 4 Patients Patient ID: 19131 3365 2294 12330 3/2/2023: 9 Patients Patient ID: 33037 24605 4623 24153 21104 34229 4872 35054 30497 3/8/2023: 6 Patients Patient ID: 3523 18807 26211 25356 8429 34461 3/13/2023: 6 Patients Patient ID: 34364 21551 31482 31067 22102 19810 3/14/2023: 5 Patients Patient ID: 3163 23177

34046 33840 24269 3/15/2023: 6 Patients Patient ID: 34632 2204 5639 34628 25444 11093 3/16/2023: 6 Patients Patient ID: 8021 30940 18259 5972 30161 12638 3/20/2023: 7 Patients Patient ID: 3890 33864 4575 9599 17865 23200 18851 3/22/2023: 8 Patients Patient ID: 22341 24686 1211 34689 34953 17332 8923 25486 3/23/2023: 5 Patients Patient ID: 16790 30805 26241 18852 25039 3/28/2023: 6 Patients Patient ID: 8155 34735 34732 13104 33451 18334 3/29/2023: 8 Patients Patient ID: 3117 999 25925 18348 17992 34394 31422 16358 5. In an interview on 5/4/2023 at approximately 15:00, in the conference room, TP 1 and the technical consultant (TC) acknowledged that the LIS acceptable expected 2SD ranges were not correct. It was stated that the laboratory had begun using a new LIS and that the acceptability ranges must have gotten shifted during the conversion, and that the laboratory failed to have a control procedure in place to ensure the detection of immediate control errors.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on a review of laboratory quality control (QC) records, patient results, and confirmed in interview, the laboratory failed to have a quality assurance (QA) mechanism in place to monitor, assess, and identify problems for QC on the Vitros Othro 350 Chemistry analyzer for three of three months reviewed from January to March 2023. The findings included: 1. Review of the laboratory quality control (QC) documents, QC instructions for use, laboratory documents, patient reports, and confirmed in interview, the laboratory failed to have a control procedure in place to detect immediate errors for five of five random analytes reviewed (Cholesterol, Glucose, Chloride, Carbon Dioxide, total Bilirubin). Refer to D5441.