

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2296675	(X3) Date Survey Completed 04/29/2024
Name of Provider or Supplier Qoros Clear Lake Surgery Center, Llc	Street Address, City, State 1240 Clear Lake City Blvd, Ste 100, Houston, 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	<p>An onsite survey conducted 04/29/2024 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.</p>
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the direct observation of the surveyor, the review of the laboratory's QC records from 03/13/2024 to 04/19/2024, patient results, and confirmed in an interview, the laboratory failed to perform two quantitative QC materials with different concentrations prior to patient testing for 7 of 7 patients on iSTAT MN 300 Analyzer. The findings were: 1. Direct observation of the surveyor on 04/29/2024 at 9:15 am revealed the laboratory had 1 iSTAT MN-300 Analyzer (SN: 433150) and the laboratory used ACT cartridges for ACT test and CG4+ cartridges for ABG test. 2. In an interview on 04/29/2024 at 09:25 am in the break room, the testing personnel #3 confirmed the first case date was 03/13/2024. 3. Review of the laboratory's patient results revealed the following 7 patients had testing performed on iSTAT analyzer without 2 levels of QC performed prior to the patient testing. 03/29/2024 at 11:09 am Test: ACT MRN: 924 03/29/2024 at 5:50 am and at 6:11 am Test: ACT MRN: 946 03/29/2024 at 9:21 am and at 9:49 am Test: ACT MRN: 954 03/29/2024 at 7:53 am Test: CG4+ MRN: 960 04/25/2024 at 9:52 am Test: ACT MRN: 1052 04/25/2024 at 8:</p>

26 am Test: ACT MRN: 1049 04/26/2024 at 10:46 am Test: ACT MRN: 1055 3. In an interview on 4/29/2024 at 11:43 am in the break room, the admin confirmed the above findings. Key: QC=Quality Control ACT=Activated Clotting Time ABG=Arterial Blood Gas MRN=Medical Record Number

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 the direct observation of the surveyor, the review of the laboratory's QC records from 03/13/2024 to 04/19/2024, patient results, and confirmed in an interview, the laboratory failed to document acceptable QC prior to reporting patient test results for 24 of 24 patients on iSTAT MN 300 Analyzer. The findings were: 1. Direct observation of the surveyor on 04/29/2024 at 9:15 am revealed the laboratory used ACT cartridges for ACT test and CG4+ cartridges for ABG test on iSTAT MN-300 Analyzer (SN: 433150). 2. In an interview on 04/29/2024 at 09:25 am in the break room, the testing personnel #3 confirmed the first case date was 03/13/2024. 3. Review of the laboratory's QC records from 03/13/2024 to 04/19/2024 revealed the laboratory used iSTAT ACT Level 1 Control Lot#: 261161 Exp.. 2024-05-31 iSTAT ACT Level 2 Control Lot#: 271161 Exp.. 2024-05-31 iSTAT TriControl Level 1 Control Lot#: 301163 iSTAT TriControl Level 3 Control Lot#: 321163 4. Further review of the laboratory's QC from 03/13/2024 to 04/19/2024 revealed the laboratory performed the following 2 levels of QC on the following dates. For ACT QC: 03/13/2024 Level 1 at 2:39 pm Level 2 at 2:24 pm 03/14/2024 Level 1 at 1:51 pm Level 2 at 1:59 pm 03/15/2024 Level 1 at 1:39 pm Level 2 at 1:46 pm 03/19/2024 Level 1 at 10:12 am Level 2 at 10:18 am 03/21/2024 Level 1 at 12:34 pm Level 2 at 12:45 pm 03/22/2024 Level 1 at 2:37 pm Level 2 at 3:10 pm 03/26/2024 Level 1 at 1:13 pm Level 2 at 12:59 pm 03/27/2024 Level 1 at 1:06 pm Level 2 at 1:12 pm 03/28/2024 Level 1 at 12:43 pm Level 2 at 12:54 pm 04/01/2024 Level 1 at 2:01 pm Level 2 at 2:07 pm 04/02/2024 Level 1 at 12:58 pm Level 2 at 1:09 pm 04/03/2024 Level 1 at 12:30 pm Level 2 at 12:27 pm 04/04/2024 Level 1 at 1:38 pm Level 2 at 1:48 pm 04/05/2024 Level 1 at 1:05 pm Level 2 at 12:55 pm 04/09/2024 Level 1 at 9:43 am Level 2 at 9:52 am 04/10/2024 Level 1 at 1:29 pm Level 2 at 1:48 pm 04/11/2024 Level 1 at 1:20 pm Level 2 at 1:26 pm 04/12/2024 Level 1 at 1:45 pm Level 2 at 1:52 pm 04/16/2024 Level 1 at 9:20 am Level 2 at 8:22 am 04/17/2024 Level 1 at 9:15 am Level 2 at 9:22 am 04/18/2024 Level 1 at 10:59 am Level 2 at 12:19 pm 04/19/2024 Level 1 at 12:51 pm Level 2 at 12:58 pm For CG4+ QC: 04/11/2024 Level 1 at 4:46 pm Level 3 at 4:41 pm 04/12/2024 Level 1 at 1:34 pm Level 3 at 1:39 pm 04/18/2024 Level 1 at 2:09 pm Level 3 at 2:16 pm 04/19/2024 Level 1 at 2:18 pm Level 3 at 2:27 pm 5. Review of patient results for the above dates and time revealed total of 24 patients had testing performed on the iSTAT analyzer. 03/13/2024 at 8:27 am Test: ACT MRN: 917 03/14/2024 at 10:52 am Test: ACT MRN: 919 03/15/2024 at 6:34 am Test: ACT MRN: 928 03/15/2024 at 9:59 am Test: ACT MRN: 918 03/19/2024 at 6:30 am Test: ACT MRN: 930 03/22/2024 at 10:29 am and at 11:01 am Test: ACT MRN: 944 03/22/2024 at 8:45 am and at 9:11 am Test: ACT MRN: 945 03/22/2024 at 6:34 am Test: ACT MRN: 946 03/27/2024 at 7:53 am and at 8:12 am Test: ACT MRN: 904 03/28/2024 at 6:24 am and at 6:50 am Test: ACT MRN: 968 04/03/2024 at 6:41 am Test: ACT MRN: 993 04/04/2024 at 6:31 am Test: ACT MRN: 917 04/05/2024 at 9:59 am Test: ACT

MRN: 992 04/05/2024 at 11:40 am Test: ACT MRN: 944 04/11/2024 at 11:05 am
Test: ACT MRN: 1004 04/11/2024 at 12:25 pm Test: ACT MRN: 1006 04/11/2024 at
09:28 am Test: ACT MRN: 945 04/11/2024 at 7:32 am Test: ACT MRN: 1007 04/12
/2024 at 7:38 am Test: ACT MRN: 984 04/12/2024 at 10:50 am Test: ACT MRN:
1003 04/12/2024 at 9:46 am and 9:52 am Test: CG4+ MRN: 965 04/17/2024 at 7:21
am Test: ACT MRN: 946 04/18/2024 at 10:01 am Test: ACT MRN: 1052 04/18/2024
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Control ACT=Activated Clotting Time ABG=Arterial Blood Gas MRN=Medical
Record Number