

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2207753	(X3) Date Survey Completed 06/14/2024
Name of Provider or Supplier Ochsner Lsu Health Shreveport Ambulatory Care	Street Address, City, State 1602 Kings Highway, Shreveport, LA	
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	A Recertification survey was performed at Ochsner LSU Health Shreveport Ambulatory Care, CLIA ID 19D2207753, on June 14, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plan (IQCP), quality control records, patient logs and interview with personnel, the laboratory failed to perform quality control (QC) for Chem 8 testing on the I-Stat analyzer every thirty (31) days of use for one (1) of eighteen (18) months reviewed in 2023 and 2024. Findings: 1. Review of the laboratory's Individualized Quality Control Plan (IQCP) revealed QC will include: 2 levels of external QC performed per lot/shipment and 2 levels of external QC performed at least once every 31 days. 2. Review of the laboratory's quality control (QC) records from January 2023 through June 14, 2024 revealed the laboratory did not perform external QC every thirty-one (31) days for the following one (1) of eighteen (18) months reviewed: a) September 2023: QC performed August 3, 2023; due September 4, 2023; not performed until October 6, 2023 3. Review of the patient test logs revealed the laboratory reported the following</p>

three hundred seventy four (374) patients for Chem 8 testing without the performance of external quality control (QC) per the laboratory's IQCP: a) September 5, 2023 at 09:43 am: Patient ID 362567755 b) September 5, 2023 at 10:04 am: Patient ID 365661236 c) September 6, 2023 at 13:29 pm: Patient ID 358353304 d) September 8, 2023 at 07:56 am: Patient ID 362521417 e) September 8, 2023 at 08:03 am: Patient ID 365793616 f) September 8, 2023 at 08:11 am: Patient ID 364173772 g) September 8, 2023 at 08:18 am: Patient ID 366446645 h) September 8, 2023 at 08:38 am: Patient ID 362608637 i) September 8, 2023 at 09:17 am: Patient ID 361303761 j) September 8, 2023 at 09:26 am: Patient ID 356489109 k) September 8, 2023 at 09:45 am: Patient ID 366940011 l) September 8, 2023 at 10:52 am: Patient ID 302880955 m) September 8, 2023 at 10:58 am: Patient ID 366829217 n) September 11, 2023 at 08:26 am: Patient ID 358272584 o) September 11, 2023 at 08:30 am: Patient ID 363776913 p) September 11, 2023 at 08:34 am: Patient ID 358136329 q) September 11, 2023 at 08:47 am: Patient ID 368034864 r) September 11, 2023 at 09:38 am: Patient ID 362595762 s) September 11, 2023 at 09:43 am: Patient ID 362595284 t) September 11, 2023 at 10:44 am: Patient ID 368741694 u) September 11, 2023 at 10:51 am: Patient ID 360431575 v) September 11, 2023 at 11:00 am: Patient ID 358776147 w) September 11, 2023 at 11:08 am: Patient ID 351676316 x) September 11, 2023 at 11:49 am: Patient ID 362596465 y) September 11, 2023 at 13:13 pm: Patient ID 368285995 z) September 11, 2023 at 13:20 pm: Patient ID 368695045 aa) September 11, 2023 at 15:33 pm: Patient ID 368283552 bb) September 12, 2023 at 08:11 am: Patient ID 358099107 cc) September 12, 2023 at 09:15 am: Patient ID 363207437 dd) September 12, 2023 at 09:19 am: Patient ID 368078482 ee) September 12, 2023 at 09:44 am: Patient ID 367541036 ff) September 12, 2023 at 10:27 am: Patient ID 365694385 gg) September 12, 2023 at 11:08 am: Patient ID 336068066 hh) September 12, 2023 at 12:25 pm: Patient ID 342064940 ii) September 12, 2023 at 12:35 pm: Patient ID 320791449 jj) September 12, 2023 at 13:30 pm: Patient ID 336038552 kk) September 12, 2023 at 13:34 pm: Patient ID 336020827 ll) September 12, 2023 at 13:38 pm: Patient ID 336015427 mm) September 12, 2023 at 13:44 pm: Patient ID 347142058 nn) September 12, 2023 at 13:50 pm: Patient ID 336045763 oo) September 12, 2023 at 13:55 pm: Patient ID 368225338 pp) September 12, 2023 at 13:59 pm: Patient ID 336064550 qq) September 12, 2023 at 14:03 pm: Patient ID 357367787 rr) September 12, 2023 at 14:07 pm: Patient ID 352074794 ss) September 12, 2023 at 14:11 pm: Patient ID 357367497 tt) September 12, 2023 at 14:15 pm: Patient ID 352111333 uu) September 12, 2023 at 14:22 pm: Patient ID 360165360 vv) September 12, 2023 at 14:30 pm: Patient ID 352059212 ww) September 12, 2023 at 14:58 pm: Patient ID 360730788 xx) September 12, 2023 at 15:03 pm: Patient ID 358237033 yy) September 12, 2023 at 15:07 pm: Patient ID 366844357 zz) September 12, 2023 at 15:30 pm: Patient ID 362780977 aaa) September 12, 2023 at 15:49 pm: Patient ID 361308473 bbb) September 12, 2023 at 16:01 pm: Patient ID 363259376 ccc) September 12, 2023 at 16:05 pm: Patient ID 363243957 ddd) September 13, 2023 at 07:56 am: Patient ID 326388958 eee) September 13, 2023 at 08:00 am: Patient ID 369228553 fff) September 13, 2023 at 08:23 am: Patient ID 321824829 ggg) September 13, 2023 at 08:47 am: Patient ID 336202808 hhh) September 13, 2023 at 09:01 am: Patient ID 368433606 iii) September 13, 2023 at 09:10 am: Patient ID 362607664 jjj) September 13, 2023 at 09:29 am: Patient ID 362109483 kkk) September 13, 2023 at 09:35 am: Patient ID 358324689 lll) September 13, 2023 at 09:39 am: Patient ID 362596397 mmm) September 13, 2023 at 09:56 am: Patient ID 352977079 nnn) September 13, 2023 at 10:05 am: Patient ID 336884839 ooo) September 13, 2023 at 10:27 am: Patient ID 360429365 ppp) September 13, 2023 at 10:57 am: Patient ID 362603818 qq) September 13, 2023 at 11:34 am: Patient ID 364644754 rrr) September 13, 2023 at 12:46 pm: Patient ID 368747726 sss) September 13, 2023 at 12:56 pm: Patient ID 362169307 ttt)

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D6020

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 the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's Individualized Quality Control Plan (IQCP), quality control records and interview with personnel, the Laboratory Director failed to ensure the quality control program was followed to assure the quality of testing in the laboratory. Refer to D5445.

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 review of the laboratory's Individualized Quality Control Plan (IQCP), quality control records and interview with personnel, the Technical Consultant failed to ensure the quality control program was followed to assure quality of laboratory testing. Refer to D5445.