

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1082041	(X3) Date Survey Completed 01/14/2021
Name of Provider or Supplier Caldwell Memorial Hospital, Inc	Street Address, City, State 411 Main Street, Columbia, 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 Complaint Survey was performed at Caldwell Memorial Hospital - CLIA ID 19D1082041 on January 14, 2021. Caldwell Memorial Hospital was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic Systems 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing, Laboratory Director
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to have complete verification studies for the Healgen COVID-19 IgG /IgM Rapid Test Cassette. Refer to D5421. 2. The laboratory failed to document positive and negative controls for the Healgen COVID-19 IgG/IgM Rapid Test Cassette. Refer to D5449.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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</p>

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 observation, record review and interview with personnel, the laboratory failed to have complete verification studies for the Healgen COVID-19 IgG/IgM Rapid Test Cassette. Findings: 1. Observation of the testing platform for Covid-19 testing on January 14, 2021 at 2:45 pm revealed the laboratory utilizes the Healgen COVID-19 IgG/IgM Rapid Test Cassette for patient testing. 2. In interview on January 14, 2021 at 3:02 pm, the new Laboratory Director stated she had only been in this position since December 7, 2020. The Laboratory Director further stated that based on review of records the laboratory started patient testing utilizing the Healgen Test Cassette in April 2020. 3. Review of laboratory's records for the Healgen COVID-19 IgG/IgM Rapid Test Cassette revealed the laboratory did not have documentation for performance verification studies to include the following: a) Accuracy b) Complete Precision 4. In interview on January 14, 2021 at 3:02 pm, the previous Laboratory Director stated the laboratory has been utilizing the Healgen test kit for screening of symptomatic patients only and was sending a confirmation swab for each patient test to a reference lab but did not keep a record of the documentition. The Laboratory Director confirmed the laboratory did not have documentation for the above cited studies.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to document positive and negative controls for the Healgen COVID-19 IgG/IgM Rapid Test Cassette. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a policy stating the frequency of which the Healgen COVID-19 IgG/IgM Rapid Test Cassette Quality Control (QC) is performed. 2. In interview on January 14, 2021 at 4:00 pm, the Laboratory Director stated there is not any commercial QC material available for the Healgen test kit. She further stated the only QC samples performed since the start of patient testing in April of 2020 was an American Proficiency Institute (API) sample on October 27, 2020 which included a positive and negative sample. 3. Review of patient records revealed a "COVID-19 Kit Testing" log which was put into use on September 17, 2020. 4. In further interview on January 14, 2021 at 4:58 pm, the Laboratory Director stated the laboratory did not keep a cumulative report for patient testing prior to September 17, 2020. 5. Review of patient records from September 17, 2020 through January 14, 2021 revealed the laboratory did not document external positive and negative quality controls (QC) each day of patient testing for the following four hundred three (403) of four hundred three (403) patients reviewed: a) Acct# 1020357 performed on

September 17, 2020 at 11:31 am b) Acct# 1020362 performed on September 17, 2020 at 17:47 pm c) Acct# 1020156 performed on September 17, 2020 at 17:51 pm d) Acct# 1020139 performed on September 18, 2020 at 10:29 am e) Acct# 1019881 performed on September 18, 2020 at 10:53 am f) Acct# 1020369 performed on September 18, 2020 at 11:08 am g) Acct# 1020265 performed on September 18, 2020 at 12:25 pm h) Acct# 1020574 performed on October 1, 2020 at 11:20 am i) Acct# 1020571 performed on October 1, 2020 at 10:53 am j) Acct# 1020572 performed on October 1, 2020 at 10:57 am k) Acct# 1020570 performed on October 1, 2020 at 10:50 am l) Acct# 1020577 performed on October 1, 2020 at 13:11 pm m) Acct# 6000111 performed on October 1, 2020 at 13:36 pm n) Acct# 1020576 performed on October 1, 2020 at 16:19 pm o) Acct# 1020584 performed on October 2, 2020 at 4:20 am p) Acct# 1020588 performed on October 5, 2020 at 9:31 am q) Acct# 1020596 performed on October 5, 2020 at 10:03 am r) Acct# 1020593 performed on October 5, 2020 at 10:00 am s) Acct# 1020591 performed on October 5, 2020 at 9:39 am t) Acct# 1020592 performed on October 5, 2020 at 9:30 am u) Acct# 1020595 performed on October 5, 2020 at 9:35 am v) Acct# 1020594 performed on October 5, 2020 at 10:12 am w) Acct# 1020597 performed on October 5, 2020 at 9:36 am x) Acct# 1020590 performed on October 5, 2020 at 9:41 am y) Acct# 1020593 performed on October 5, 2020 at 10:00 am z) Acct# 1020598 performed on October 5, 2020 at 10:05 am a2) Acct# 1020675 performed on October 12, 2020 at 12:07 pm b2) Acct# 1020676 performed on October 12, 2020 at 10:20 am c2) Acct# 1020681 performed on October 12, 2020 at 11:48 am d2) Acct# 1020696 performed on October 13, 2020 at 10:45 am e2) Acct# 1020699 performed on October 13, 2020 at 11:19 am f2) Acct# 1020695 performed on October 13, 2020 at 11:38 am g2) Acct# 1020706 performed on October 14, 2020 at 9:14 am h2) Acct# 1020707 performed on October 14, 2020 at 9:14 am i2) Acct# 1020717 performed on October 14, 2020 at 10:21 am j2) Acct# 1020713 performed on October 14, 2020 at 10:50 am k2) Acct# 1020724 performed on October 14, 2020 at 11:40 am l2) Acct# 1020723 performed on October 14, 2020 at 11:40 am m2) Acct# 1020725 performed on October 14, 2020 at 11:40 am n2) Acct# 1020726 performed on October 14, 2020 at 12:00 pm o2) Acct# 1020727 performed on October 14, 2020 at 12:27 pm p2) Acct# 1020712 performed on October 14, 2020 at 12:58 pm q2) Acct# 1020736 performed on October 15, 2020 at 09:10 am r2) Acct# 1020745 performed on October 15, 2020 at 10:20 am s2) Acct# 1020756 performed on October 15, 2020 at 11:35 am t2) Acct# 1020757 performed on October 15, 2020 at 11:37 am u2) Acct# 1020754 performed on October 15, 2020 at 12:47 pm v2) Acct# 1020801 performed on October 20, 2020 at 14:52 pm w2) Acct# 1020822 performed on October 21, 2020 at 08:35 am x2) Acct# 1000579 performed on October 21, 2020 at 16:05 pm y2) Acct# 1020848 performed on October 22, 2020 at 09:35 am z2) Acct# 1020853 performed on October 22, 2020 at 09:54 am a3) Acct# 1020855 performed on October 22, 2020 at 11:00 am b3) Acct# 1020856 performed on October 22, 2020 at 11:10 am c3) Acct# 1020864 performed on October 22, 2020 at 11:44 am d3) Acct# 1020866 performed on October 22, 2020 at 12:43 pm e3) Acct# 1020867 performed on October 22, 2020 at 12:43 pm f3) Acct# 1020868 performed on October 22, 2020 at 13:12 pm g3) Acct# 1020875 performed on October 23, 2020 at 09:37 am h3) Acct# 1020879 performed on October 23, 2020 at 09:57 am i3) Acct# 1020878 performed on October 23, 2020 at 09:42 am j3) Acct# 1020881 performed on October 23, 2020 at 10:20 am k3) Acct# 1020882 performed on October 23, 2020 at 10:54 am l3) Acct# 1020887 performed on October 23, 2020 at 12:20 pm m3) Acct# 1020891 performed on October 25, 2020 at 06:25 am n3) Acct# 1020906 performed on October 26, 2020 at 11:12 am o3) Acct# 1020907 performed on October 26, 2020 at 11:15 am p3) Acct# 1020908 performed on October 26, 2020 at 11:17 am q3) Acct# 1020911 performed on October 26, 2020 at 09:03 am r3) Acct# 1020904 performed on October 26, 2020 at

11:40 am s3) Acct# 1020913 performed on October 26, 2020 at 12:01 pm t3) Acct# 1020914 performed on October 26, 2020 at 13:00 pm u3) Acct# 1020916 performed on October 26, 2020 at 13:06 pm v3) Acct# 1020917 performed on October 26, 2020 at 13:32 pm w3) Acct# 1021017 performed on October 30, 2020 at 08:50 am x3) Acct# 1021019 performed on October 30, 2020 at 09:19 am y3) Acct# 1021018 performed on October 30, 2020 at 09:21 am z3) Acct# 1021020 performed on October 30, 2020 at 09:20 am a4) Acct# 1021021 performed on October 30, 2020 at 09:17 am b4) Acct# 1021022 performed on October 30, 2020 at 09:25 am c4) Acct# 1021027 performed on October 30, 2020 at 10:24 am d4) Acct# 1021029 performed on October 30, 2020 at 12:52 pm e4) Acct# 1021028 performed on October 30, 2020 at 12:56 pm f4) Acct# 1021033 performed on November 2, 2020 at 08:21 am g4) Acct# 1021052 performed on November 3, 2020 at 07:45 am h4) Acct# 1021053 performed on November 3, 2020 at 07:45 am i4) Acct# 1021054 performed on November 3, 2020 at 07:45 am j4) Acct# 1021055 performed on November 3, 2020 at 07:45 am k4) Acct# 1021056 performed on November 3, 2020 at 07:45 am l4) Acct# 1021058 performed on November 3, 2020 at 08:47 am m4) Acct# 1021061 performed on November 3, 2020 at 10:02 am n4) Acct# 1021062 performed on November 3, 2020 at 10:25 am o4) Acct# 1021067 performed on November 3, 2020 at 13:04 pm p4) Acct# 1021068 performed on November 3, 2020 at 13:48 pm q4) Acct# 1021069 performed on November 3, 2020 at 14:27 pm r4) Acct# 1021070 performed on November 3, 2020 at 15:28 pm s4) Acct# 1021074 performed on November 4, 2020 at 08:46 am t4) Acct# 1021078 performed on November 4, 2020 at 09:18 am u4) Acct# 1020976 performed on November 4, 2020 at 08:50 am v4) Acct# 1021079 performed on November 4, 2020 at 09:20 am w4) Acct# 1021096 performed on November 5, 2020 at 09:00 am x4) Acct# 1021109 performed on November 5, 2020 at 12:58 pm y4) Acct# 1021127 performed on November 6, 2020 at 13:01 pm z4) Acct# 1021129 performed on November 6, 2020 at 13:46 pm a5) Acct# 1021131 performed on November 6, 2020 at 14:50 pm b5) Acct# 1021132 performed on November 6, 2020 at 15:35 pm c5) Acct# 1021137 performed on November 9, 2020 at 08:41 am d5) Acct# 1021136 performed on November 9, 2020 at 08:41 am e5) Acct# 1021138 performed on November 9, 2020 at 09:13 am f5) Acct# 1021116 performed on November 5, 2020 at 13:42 pm g5) Acct# 1021118 performed on November 6, 2020 at 08:26 am h5) Acct# 1021120 performed on November 6, 2020 at 10:04 am i5) Acct# 1021124 performed on November 6, 2020 at 10:37 am j5) Acct# 1021123 performed on November 6, 2020 at 10:38 am k5) Acct# 1021122 performed on November 6, 2020 at 10:38 am l5) Acct# 1021126 performed on November 6, 2020 at 10:42 am m5) Acct# 1021139 performed on November 9, 2020 at 09:13 am n5) Acct# 1021141 performed on November 9, 2020 with no time documented o5) Acct# 1021140 performed on November 9, 2020 09:27 am p5) Acct# 1021143 performed on November 9, 2020 at 09:43 am q5) Acct# 1021145 performed on November 9, 2020 at 10:04 am r5) Acct# 1021148 performed on November 9, 2020 at 10:36 am s5) Acct# 1021150 performed on November 9, 2020 at 10:15 am t5) Acct# 1021155 performed on November 9, 2020 at 11:00 am u5) Acct# 1021154 performed on November 9, 2020 at 11:09 am v5) Acct# 1021156 performed on November 9, 2020 at 11:10 am w5) Acct# 1021160 performed on November 9, 2020 at 11:31 am x5) Acct# 1021159 performed on November 9, 2020 at 11:36 am y5) Acct# 1021176 performed on November 10, 2020 at 09:59 am z6) Acct# 1021182 performed on November 10, 2020 at 10:32 am a7) Acct# 1021186 performed on November 10, 2020 at 11:22 am b7) Acct# 1021188 performed on November 10, 2020 at 12:19 pm c7) Acct# 1021184 performed on November 10, 2020 at 12:34 pm d7) Acct# 1021185 performed on November 10, 2020 at 15:10 pm e7) Acct# 1021193 performed on November 10, 2020 at 1550 pm f7) Acct# 1021205 performed on November 11, 2020 at 12:51 pm g7) Acct# 1021214 performed on November 11,

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u9) Acct# 1021398 performed on November 20, 2020 at 13:35 pm v9) Acct# 1021406 performed on November 20, 2020 at 15:52 pm w9) Acct# 1021408 performed on November 23, 2020 at 08:21 am x9) Acct# 1021409 performed on November 23, 2020 at 08:54 am y9) Acct# 1021411 performed on November 23, 2020 at 09:24 am z9) Acct# 1021415 performed on November 23, 2020 at 10:36 am a10) Acct# 1021420 performed on November 23, 2020 at 11:18 am b10) Acct# 1021419 performed on November 23, 2020 at 11:18 am c10) Acct# 1021431 performed on November 24, 2020 at 08:02 am d10) Acct# 1021430 performed on November 24, 2020 at 08:00 am e) Acct# 101021428 performed on November 24, 2020 at 07:54 am f10) Acct# 1021427 performed on November 24, 2020 at 07:55 am g10) Acct# 1021355 performed on November 24, 2020 at 08:25 am h10) Acct# 1021438 performed on November 24, 2020 at 09:26 am i10) Acct# 1021440 performed on November 24, 2020 at 13:25 pm j10) Acct# 1021441 performed on November 24, 2020 at 15:12 pm k10) Acct# 1021442 performed on November 24, 2020 at 15:14 pm l10) Acct# 1021446 performed on November 25, 2020 at 09:03 am m10) Acct# 1021447 performed on November 25, 2020 at 09:29 am n10) Acct# 1021450 performed on November 25, 2020 at 10:02 am o10) Acct# 1021452 performed on November 25, 2020 at 11:48 am p10) Acct# 1021456 performed on November 25, 2020 at 13:26 pm q10) Acct# 1021255 performed on November 25, 2020 at 13:50 pm r10) Acct# 1021459 performed on November 25, 2020 at 13:48 pm s10) Acct# 1021255 performed on November 25, 2020 at 13:55 pm t10) Acct# 1021457 performed on November 25, 2020 at 14:30 pm u10) Acct# 1021466 performed on November 30, 2020 at 08:44 am v10) Acct# 1021468 performed on November 30, 2020 at 09:02 am w10) Acct# 1021469 performed on November 30, 2020 at 09:02 am x10) Acct# 1021471 performed on November 30, 2020 at 09:53 am y10) Acct# 1021476 performed on November 30, 2020 at 11:55 am z10) Acct# 1021481 performed on November 30, 2020 at 11:41 am a11) Acct# 1021484 performed on November 30, 2020 at 11:58 am b11) Acct# 1021483 performed on November 30, 2020 at 12:58 pm c11) Acct# 1021490 performed on November 30, 2020 at 15:00 pm d11) Acct# 1021491 performed on November 30, 2020 at 15:05 pm e11) Acct# 1021494 performed on November 30, 2020 at 16:01 pm f11) Acct# 10215555 performed on December 4, 2020 at 06:11 am g11) Acct# 1021563 performed on December 4, 2020 at 09:19 am h11) Acct# 1021564 performed on December 4, 2020 at 09:54 am i11) Acct# 1021565 performed on December 4, 2020 at 10:05 am j11) Acct# 1021567 performed on December 4, 2020 at 10:41 am k11) Acct# 1021569 performed on December 4, 2020 at 10:42 am l11) Acct# 1021571 performed on December 4, 2020 at 14:57 pm m11) Acct# 10215555 performed on December 5, 2020 at 05:41 am n11) Acct# 1021457 performed on December 7, 2020 at 06:25 am o11) Acct# 1021547 performed on December 7, 2020 at 09:11 am p11) Acct# 1021587 performed on December 7, 2020 at 10:30 am q11) Acct# 1021590 performed on December 7, 2020 at 11:10 am r11) Acct# 1021592 performed on December 7, 2020 at 11:07 am s11) Acct# 1021579 performed on December 7, 2020 at 11:26 am t11) Acct# 1021595 performed on December 7, 2020 at 11:45 am u11) Acct# 1021596 performed on December 7, 2020 at 11:54 am v11) Acct# 1021597 performed on December 7, 2020 at 12:17 pm w11) Acct# 1021594 performed on December 7, 2020 at 12:09 pm x11) Acct# 1021601 performed on December 7, 2020 at 12:58 pm y11) Acct# 1021603 performed on December 7, 2020 at 13:36 pm z11) Acct# 1021604 performed on December 7, 2020 at 13:36 pm a12) Acct# 1021598 performed on December 7, 2020 at 13:50 pm b12) Acct# 1021605 performed on December 7, 2020 at 15:02 pm c12) Acct# 1021602 performed on December 7, 2020 at 15:08 pm d12) Acct# 1021613 performed on December 8, 2020 at 08:06 am e12) Acct# 1021621 performed on December 8, 2020 at 09:44 am f12) Acct# 1021622 performed on December 8, 2020 at 09:44 am g12) Acct# 1021623 performed on December 8,

2020 at 09:44 am h12) Acct# 1021629 performed on December 8, 2020 at 10:21 am i12) Acct# 1021635 performed on December 8, 2020 at 10:43 am j12) Acct# 1021637 performed on December 8, 2020 at 10:56 am k12) Acct# 1021633 performed on December 8, 2020 at 11:10 am l12) Acct# 1021645 performed on December 8, 2020 at 11:39 am m12) Acct# 1021664 performed on December 9, 2020 at 09:51 am n12) Acct# 1021665 performed on December 9, 2020 at 09:39 am o12) Acct# 1021672 performed on December 9, 2020 at 10:35 am p12) Acct# 1021674 performed on December 9, 2020 at 10:35 am q12) Acct# 1021675 performed on December 9, 2020 at 10:40 am r12) Acct# 1021679 performed on December 9, 2020 at 11:37 am s12) Acct# 1021670 performed on December 9, 2020 at 12:25 pm t12) Acct# 1021684 performed on December 9, 2020 at 13:12 pm u12) Acct# 1021685 performed on December 9, 2020 at 13:10 pm v12) Acct# 1021727 performed on December 11, 2020 at 14:40 pm w12) Acct# 1021728 performed on December 11, 2020 at 14:50 pm x12) Acct# 1021729 performed on December 11, 2020 at 15:05 pm y12) Acct# 1021732 performed on December 11, 2020 at 16:07 pm z12) Acct# 1021736 performed on December 14, 2020 at 09:30 am a13) Acct# 1021739 performed on December 14, 2020 at 10:28 am b13) Acct# 1021738 performed on December 14, 2020 at 10:28 am c13) Acct# 1021741 performed on December 14, 2020 at 10:29 am d13) Acct# 1021740 performed on December 14, 2020 at 10:29 am e13) Acct# 1021747 performed on December 14, 2020 at 10:06 am f13) Acct# 1021689 performed on December 14, 2020 at 11:35 am g13) Acct# 1021688 performed on December 14, 2020 at 11:48 am h13) Acct# 1021751 performed on December 14, 2020 at 13:19 pm i13) Acct# 1021752 performed on December 14, 2020 at 13:20 pm j13) Acct# 1021753 performed on December 14, 2020 at 13:40 pm k13) Acct# 1021754 performed on December 14, 2020 at 14:30 pm l13) Acct# 1021757 performed on December 14, 2020 at 15:53 pm m13) Acct# 1021758 performed on December 14, 2020 at 16:32 pm n13) Acct# 1021765 performed on December 15, 2020 at 09:06 am o13) Acct# 1021780 performed on December 15, 2020 at 09:43 am p13) Acct# 1021778 performed on December 15, 2020 at 12:30 pm r13) Acct# 1021779 performed on December 15, 2020 at 12:36 pm s13) Acct# 1021783 performed on December 15, 2020 at 13:34 pm t13) Acct# 1021786 performed on December 15, 2020 at 14:15 pm u13) Acct# 1021787 performed on December 15, 2020 at 14:25 pm v13) Acct# 1021766 performed on December 15, 2020 at 15:02 pm w13) Acct# 1021788 performed on December 15, 2020 at 15:37 pm x13) Acct# 1021789 performed on December 15, 2020 at 16:12 pm y13) Acct# 1021791 performed on December 16, 2020 at 08:28 am z13) Acct# 1021794 performed on December 16, 2020 at 08:56 am a14) Acct# 1021795 performed on December 16, 2020 at 09:09 am b14) Acct# 1021796 performed on December 16, 2020 at 09:05 am c14) Acct# 1021798 performed on December 16, 2020 at 09:26 am d14) Acct# 1021803 performed on December 16, 2020 at 10:07 am e14) Acct# 1021810 performed on December 16, 2020 at 10:59 am f14) LAB 57839 performed on on December 16, 2020 at 11:07 am g14) Acct# 1021813 performed on December 16, 2020 at 12:30 pm h14) Acct# 1021816 performed on December 16, 2020 at 14:55 pm i14) LAB 57891 performed on December 16, 2020 at 15:47 pm j14) Acct# 1021833 performed on December 17, 2020 at 10:21 am k14) Acct# 1021842 performed on December 17, 2020 at 11:23 am l14) Acct# 1021845 performed on December 18, 2020 at 08:48 am m14) Acct# 1021846 performed on December 18, 2020 at 09:03 am n14) Acct# 1021847 performed on December 18, 2020 at 12:34 pm o14) Acct# 1021852 performed on December 18, 2020 at 12:59 pm p14) Acct# 1021853 performed on December 18, 2020 at 14:48 pm q14) Acct# 1021854 performed on December 18, 2020 at 15:55 pm r14) Acct# 1021860 performed on December 21, 2020 at 09:58 am s14) Acct# 1021861 performed on December 21, 2020 at 10:33 am t14) Acct# 1021862 performed on December 21, 2020 at 10:38 am u14) Acct# 1021869

performed on December 21, 2020 at 15:56 pm v14) Acct# 1021874 performed on December 22, 2020 at 09:15 am w14) Acct# 1021873 performed on December 22, 2020 at 09:31 am x14) Acct# 1021879 performed on December 22, 2020 at 13:20 pm y14) Acct# 1021881 performed on December 23, 2020 at 11:25 am z14) Acct# 1021885 performed on December 23, 2020 at 12:11 pm a15) Acct# 1021887 performed on December 23, 2020 at 12:15 pm b15) Acct# 1021888 performed on December 23, 2020 at 12:42 pm c15) Acct# 1021889 performed on December 23, 2020 at 14:40 pm d15) Acct# 1021890 performed on December 23, 2020 at 15:27 pm e15) Acct# 1021891 performed on December 23, 2020 at 16:45 pm f15) Acct# 1021897 performed on December 24, 2020 at 09:54 am g15) Acct# 1021899 performed on December 24, 2020 at 10:43 am h15) Acct# 1021898 performed on December 24, 2020 at 10:40 am i15) Acct# 1021906 performed on December 28, 2020 at 09:04 am j15) Acct# 1021908 performed on December 28, 2020 at 10:10 am k15) Acct# 1021909 performed on December 28, 2020 at 11:07 am l15) Acct# 1021910 performed on December 28, 2020 at 11:22 am m15) Acct# 1021905 performed on December 28, 2020 at 11:50 am n15) Acct# 1021908 performed on December 28, 2020 at 12:09 pm o15) Acct# 1021904 performed on December 28, 2020 at 13:17 pm p15) Acct# 1021913 performed on December 28, 2020 at 14:04 pm q15) Acct# 1021914 performed on December 28, 2020 at 14:26 pm r15) Acct# 1021917 performed on December 28, 2020 at 15:06 pm s15) Acct# 1021919 performed on December 28, 2020 at 16:15 pm t15) Acct# 1021923 performed on December 29, 2020 at 08:43 am u15) Acct# 1021816 performed on December 29, 2020 at 09:06 am v15) Acct# 1021925 performed on December 29, 2020 at 09:43 am w15) Acct# 1021928 performed on December 29, 2020 at 10:30 am x15) Acct# 1021934 performed on December 29, 2020 at 11:25 am y15) Acct# 1021936 performed on December 29, 2020 at 11:13 am z15) Acct# 1021938 performed on December 29, 2020 at 11:31 am a16) Acct# 1021943 performed on December 29, 2020 at 08:52 am b16) Acct# 1021949 performed on December 29, 2020 at 11:40 am c16) Acct# 1021958 performed on December 31, 2020 at 09:14 am d16) Acct# 1021959 performed on December 31, 2020 at 09:13 am e16) Acct# 6000094 performed on January 2, 2021 at 12:58 pm f16) LAB 59617 performed on January 4, 2021 at 09:00 am g16) Acct# 1021964 performed on January 4, 2021 at 08:51 am h16) Acct# 1021965 performed on January 4, 2021 at 08:51 am i16) Acct# 1021969 performed on January 4, 2021 at 09:45 am j16) Acct# 1021970 performed on January 4, 2021 at 09:48 am k16) Acct# 1021972 performed on January 4, 2021 at 11:00 am l16) Acct# 1021971 performed on January 4, 2021 at 11:07 am m16) Acct# 1021974 performed on January 4, 2021 at 11:24 am n16) Acct# 1021975 performed on January 4, 2021 at 11:36 am o16) Acct# 1021982 performed on January 4, 2021 at 1555 pm p16) Acct# 1021983 performed on January 4, 2021 at 16:15 pm q16) Acct# 1021984 performed on January 4, 2021 at 16:45 pm r16) Acct# 1021995 performed on January 4, 2021 at 10:11 am s16) Acct# 1022002 performed on January 5, 2021 at 10:49 am t16) Acct# 1022017 performed on January 5, 2021 at 15:47 pm u16) Acct# 1022025 performed on January 6, 2021 at 09:50 am v16) Acct# 1022026 performed on January 6, 2021 at 09:40 am w16) Acct# 1022027 performed on January 6, 2021 at 09:43 am x16) Acct# 1022028 performed on January 6, 2021 at 09:47 am y16) Acct# 1022048 performed on January 6, 2021 at 11:26 am z16) Acct# 1022058 performed on January 6, 2021 at 13:53 pm a17) Acct# 1022059 performed on January 6, 2021 at 14:20 pm b17) Acct# 1022063 performed on January 7, 2021 at 04:45 am c17) Acct# 1022081 performed on January 7, 2021 at 12:14 pm d17) Acct# 1022084 performed on January 7, 2021 at 14:18 pm e17) Acct# 1022090 performed on January 8, 2021 at 09:13 am f17) Acct# 1022103 performed on January 12, 2021 at 08:30 am g17) Acct# (no identifier only patient name recorded) performed on January 12, 2021 at 11:19 am h17) Acct# 1022117 performed on January 12, 2021 at 13:03 pm i17) Acct# 1022137

performed on January 13, 2021 at 10:41 am j17) Acct# 1022140 performed on January 13, 2021 at 10:41 am k17) Acct# 1022145 performed on January 13, 2021 at 12:24 pm 6. In interview on January 14, 2021 at 4:50 pm, the Laboratory Director confirmed external QC was not performed for each of the above cited patients.

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 interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D6013. 2. The Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D6020.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.

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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D5449.