

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0283933	(X3) Date Survey Completed 08/13/2024
Name of Provider or Supplier Hca Florida Aventura Hospital	Street Address, City, State 20900 Biscayne Blvd, Aventura, FL	
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
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 review of the laboratory's College of American Pathologist (CAP) proficiency testing (PT) records from 2023 and 2024, and staff interview on August 13, 2024 at 09:45 am, the laboratory failed to test blood gas proficiency testing samples on the laboratory's Siemens Epop System in the same manner as it tested its patient samples for 4 of 5 PT events in 2023 and 2024. Findings include: 1. A review of the laboratory's CAP testing records from 2023 and 2024 revealed the laboratory tested PT samples multiples times with the same operators, for the following testing events: a) 2023 Blood Gas 1st Event ("AQ-A 2023 Critical Care Blood Gas w /Chemistry"), Kit ID: 37159326, CAP #: 1493501-01, March 14, 2023: i. User KEQ6427 - HCT-A-04, 11:00:20 Card lot: 04-22318-30 Reader: 34501 Test Type: Proficiency eVAD version: epoc22340 ii. User KEQ6427 - AQ-A-04, 10:22:19 Card lot: 04-23012-50 Reader: 34448 Test Type: Proficiency eVAD version: epoc22340 iii. User KEQ6427 - HCT-A-05, 14:44:30 Card lot: 04-22318-30 Reader: 34448 Test Type: Proficiency eVAD version: epoc22340 iv. User KEQ6427 - AQ-A-05, 10:30:39 Card lot: 23012-50 Reader: 34448 Test Type: Proficiency eVAD version: epoc22340 b) 2023 Blood Gas 2nd Event ("AQ-B 2023 Critical Care Blood Gas w/Chemistry"), Kit ID: 37159335, CAP #: 1493501-01, July 18, 2023: i. User OPT4367 - HCT- 06, 14-Jul-23, 12:47:57 Card lot: 04-23138-20 Reader: 34302 Test Type: Proficiency eVAD version: epoc23110 ii. User OPT4367 - AQ-B-06, 14-Jul-23, 12:19:16 Card lot: 04-23138-20 Reader: 34302 Test Type: Proficiency eVAD version: epoc23110 iii. User KZE874 - HCT-07, 14-Jul-23, 12:49:15 Card lot: 04-23138-20 Reader: 34448 Test Type: Proficiency eVAD version: epoc23110 iv. User KZE874 - AQ-B-07, 14-Jul-23, 12:20:35 Card lot: 04-23138-20 Reader: 34448 Test Type: Proficiency eVAD</p>

version: epoc23110 v. User OPT4367 - HCT-08, 14-Jul-23, 12:57:05 Card lot: 04-23138-20 Reader: 34302 Test Type: Proficiency eVAD version: epoc23110 vi. User OPT4367 - AQ-B-08, 14-Jul-23, 12:28:32 Card lot: 04-23138-20 Reader: 34302 Test Type: Proficiency eVAD version: epoc23110 c) 2023 Blood Gas 3rd Event ("AQ-C 2023 Critical Care Blood Gas w/Chemistry"), Kit ID: 3715934420685, CAP #: 1493501-01, November 07, 2023 i. User KZE8741 - AQ-C 2023 AQ-12, 20-Oct-23, 9:10:51 Card lot: 04-23192-20 Reader: 34330 Test Type: Proficiency eVAD version: epoc23221 ii. User KZE8741 - AQ-C 2023 hte-12, 20-Oct-23 09:41:54 Card lot: 04-23192-20 Reader: 34330 Test Type: Proficiency iii. User KZE8741 - AQ-C 2023 AQ-14, 20-Oct-23 09:21:22 Card lot: 04-23192-20 Reader: 34448 Test Type: Proficiency eVAD version: epoc23221 iv. User KZE8741 - AQ-C 2023 the-14, 20-OCT-23 09:50:00 Card lot: 04-23192-20 Reader: 34330 Test Type: Proficiency eVAD version: epoc23221 2. A review of the laboratory's CAP testing records from 2023 and 2024 revealed the laboratory tested PT samples multiple times with different operators, for the following testing events: a) 2023 Blood Gas 1st Event ("AQ-A 2023 Critical Care Blood Gas w/Chemistry"), Kit ID: 37159326, CAP #: 1493501-01, March 14, 2023: i. User KEQ6427 - HCT-A-01, 09-Mar-23, 10:30:35 Card lot: 04-22318-30 Reader: 34591 Test Type: Proficiency eVAD version: epoc22340 ii. User KZE8741 - AQ-A-01, 09-Mar-23, 10:35:15 Card lot: 04-23012-50 Reader: 34448 Test Type: Proficiency eVAD version: epoc22340 iii. User KEQ6427 - HCT-A-02, 09-Mar-23, 10:41:11 Card lot: 04-22318-30 Reader: 34501 Test Type: Proficiency eVAD version: epoc22340 iv. User KZE8741 - AQ-A-02, 09-Mar-23, 10:46:18 Card lot: 04-23012-50 Reader: 34448 Test Type: Proficiency eVAD version: epoc22340 v. User KEQ6427 - HCT-A-03, 10:50:41 Card lot: 04-22318-30 Reader: 34501 Test Type: Proficiency eVAD version: epoc22340 vi. User KZE8741 - AQ-A-03, 10:55:39 Card lot: 04-23012-50 Reader: 34448 Test Type: Proficiency eVAD version: epoc22340 b) 2023 Blood Gas 2nd Event ("AQ-B 2023 Critical Care Blood Gas w/Chemistry"), Kit ID: 37159335, CAP #: 1493501-01, July 18, 2023: i. User KZE8741 - HCT-09, 14-Jul-23, 12:58:17 Card lot: 04-23138-20 Reader: 34448 Test Type: Proficiency eVAD version: epoc23110 ii. User OPT4367 - AQ-B-09, 18-Jul-23, 10:07:42 Card lot: 04-23117-30 Reader: 34448 Test Type: Proficiency eVAD version: epoc23110 iii. User KZE8741 - HCT-10, 14-Jul-23, 12:39:15 Card lot: 04-23138-20 Reader: 34448 Test Type: Proficiency eVAD version: epoc23110 iv. User OPT4367 - AQ-B-10, 14-Jul-23, 12:38:06 Card lot: 04-23138-20 Reader: 34302 Test Type: Proficiency eVAD version: epoc23110 c) 2023 Blood Gas 3rd Event ("AQ-C 2023 Critical Care Blood Gas w/Chemistry"), Kit ID: 3715934420685, CAP #: 1493501-01, November 07, 2023 i. User KZE8741 - AQ-C 2023, AQ-11, 20-Oct-23, 9:12:37 Card lot: 04-23192-20 Reader: 34448 Test Type: Proficiency eVAD version: epoc23221 ii. User OPT4367 - AQ-C 2023 hte-11, 20-Oct-23, 09:39:45 Card lot: 04-23192-20 Reader: 34448 Test Type: Proficiency eVAD version: epoc23221 iii. User KZE8741 - AQ-C 2023 AQ-13, 20-Oct-23, 9:19:55 Card lot: 04-23192-20 Reader: 34330 Test Type: Proficiency eVAD version: epoc23221 iv. User OPT4367 - AQ-C 2023 hte-13, 20-Oct-23, 09:48:31 Card lot: 04-23192-20 Reader: 34448 Test Type: Proficiency eVAD version: epoc23221 v. User KZE8741 - AQ-C 2023 AQ-15, 20-Oct-23, 09:32:36 Card lot: 04-23192-20 Reader: 34330 Test Type: Proficiency eVAD version: epoc23221 vi. User OPT4367 - AQ-C 2023 hte-15, 20-Oct-23, 09:56:24 Card lot: 04-23192-20 Reader: 34448 Test Type: Proficiency eVAD version: epoc23221 d) 2024 Blood Gas 2nd Event ("AQ-C 2023 Critical Care Blood Gas with Hematocrit"), Kit ID: 3845743370131, CAP #: 1493501-01, July 09, 2024 i. User CLY0786 - AQB2024-06, 05-Jul-24, 09:19:10 Card lot: 08-24130-50 Reader: 34330 Test Type: Proficiency eVAD version: epoc24123 ii. User KZE8741 - AQB2024-06, 05-July-24, 09:19:35 Card lot: 08-24130-50 Reader: 34448 Test Type: Proficiency eVAD version: epoc24123 iii. User CLY0786 - AQB2024-07, 05-Jul-24, 09:29:31

Card lot: 08-24130-50 Reader: 34330 Test Type: Proficiency eVAD version: epoc24123 iv. User KZE8741 - AQB2024-07, 05-Jul-24, 09:30:20 Card lot: 08-24130-50 Reader: 34448 Test Type: Proficiency eVAD version: epoc24123 v. User KZE8741 - AQB2024-08, 05-Jul-24, 09:40:57 Card lot: 08-24130-50 Reader: 34448 Test Type: Proficiency eVAD version: epoc24123 vi. User CLY0786 - AQB2024-08, 05-Jul-24, 09:41:41 Card lot: 08-24130-50 Reader: 34330 Test Type: Proficiency eVAD version: epoc24123 vii. User KZE8741 - AQB2024-09, 05-Jul-24, 09:50:49 Card lot: 08-24130-50 Reader: 34448 Test Type: Proficiency eVAD version: epoc24123 viii. User CLY0786 - AQB2024-09, 05-Jul-24, 09:51:40 Card lot: 08-24130-50 Reader: 34448 Test Type: Proficiency eVAD version: epoc24123 ix. User OPT4367 - AQB2024-10, 05-Jul-24, 10:14:41 Card lot: 08-24130-50 Reader: 34330 Test Type: Proficiency eVAD version: epoc24123 x. User KZE8741 - AQB2024-10, 05-Jul-24, 10:15:27 Card lot: 08-24130-50 Reader: 34330 Test Type: Proficiency eVAD version: epoc24123 3. In an interview on 8/14/2024 at 9:45 am in the facility's conference room, laboratory personnel confirmed that patient samples are not run in duplicate on the same or different instruments by the same or different testing personnel before reporting blood gas patient test results, corroborating the findings above.