Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0665024	06/04/2021
Name of Provider or Supplier	**Street Address, City, State**	
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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	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D1000	Based on review of the manufacturer's instructions, laboratory records from June 2020 to June 2021, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions to document quality control using the Medline Evencare G2 blood glucose test strips for 22 of 22 weeks reviewed. Findings included: 1. Review of the Medline Evencare G2 blood glucose test strips package insert (P/N 65056000069, Rev 11/18) under quality control revealed "run low and high control solution tests. Follow the User's guide instructions. Do control tests: -at least once per week to make sure the meter and test strips are working properly -every time you open a new bottle of test strips" 2. Review of the laboratory records from 6/5/20 to 6/4 /21 revealed the laboratory performed 29 glucose testing using the Medline Evencare G2 blood glucose test strips. date patient ID 06/10/2020 4778 06/11/2020 9079 06/19 /2020 5602 06/23/2020 3550 07/27/2020 423 08/04/2020 5453 09/03/2020 1961 09/09 /2020 9367 09/11/2020 7737 09/11/2020 7737 09/15/2020 5446 09/22/2020 7737 09 /29/2020 9510 10/09/2020 62 10/16/2020 9581 10/21/2020 1000 10/23/2020 4014 11 /20/2020 4938 11/23/2020 3125 12/03/2020 7950 01/05/2021 7934 01/14/2021 9559 01/21/2021 3289 03/05/2021 9935 03/31/2021 4855 04/12/2021 1254 05/05/2021 5327 05/06/2021 5514 05/12/2021 7902 3. Review of the laboratory records from 6/5 /20 to 6/4/21 revealed no documentation of the high and low quality control for 22 of 22 weeks reviewed when the above testing were performed. 4. An interview with the testing person # 1 on 6/4/21 at 1215 hours in the office confirmed the above findings.
D2009	Based on review of the CMS national database, laboratory's American Proficiency Institute's proficiency testing records from 2019 to 2021 and confirmed in interview, the laboratory failed to have documentation of the laboratory director or designee and

	testing person signing 5 of 7 attestation statements reviewed. The findings were: 1. A review of the CMS national database from 2019 to 2021 revealed the laboratory participated in the following 5 test events. 2021 Hematology 1st event 2020 Hematology 2nd event 2020 Hematology 3rd event 2019 Hematoloty 1st event 2019 Hematology 2nd event 2. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2019 to 2021 revealed no documentation of the laboratory director or designee and testing person signing 5 of 7 attestation statements. 2021 Hematology 1st event 2020 Hematology 2nd event 2020 Hematology 3rd event 2019 Hematoloty 1st event 2019 Hematology 2nd event 3. An interview with facility manager on 6/4/21 at 1005 hours in the office and after her review of the records confirmed the findings.
D3000	Based on review of the manufacturer's instructions, laboratory and patient test records from 2020-2021, and confirmed in interview, the laboratory failed to report 807 SARS-CoV-2 negative Antigen test results as required by 400.200 for 136 of 136 days reviewed from 10/1/2020 to 6/4/2021. Findings were: 1. Review of the Instructions for Use for the BD Veritor of SARS-CoV-2 & Flu A + B (256088, 500051910(01), 2021-03) under Reporting of Results revealed "Testing facilities within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities." 2. Review of the laboratory test records from 2020 to 2021 revealed the laboratory started SARS-CoV-2 Antigen patient testing using BD Veritor of SARS-CoV-2 & Flu A + B test on 11/4/20. 3. Review of the Instructions for Use for the Sofia 2 Flu + SARS Antigen FIA test cassettes under CONDITIONS OF AUTHORIZATION FOR THE LABORATORY revealed "authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 4. Review of the laboratory test records from 2020 to 2021 revealed the laboratory started SARS-CoV-2 Antigen patient testing Sofia 2 Flu + SARS Antigen FIA test cassettes on 9/21/20. 5. Review of the laboratory policies available revealed no documentation of a policy/procedure related to SARS-CoV-2 test reporting. 6. Review of the laboratory SARS-CoV-2 Antigen patient test records from 2020 to 2021 revealed no documentation the laboratory reported 807 patient negative test records for 136 of 136 days of testing. Refer to Covid Antigen Patient Alias list. 7. An interview with the testing person #1 on 6/4/21 at 1155 hours in the office confirmed the above findings
D3031	Based on a random review of the laboratory patient logs from 2020 to 2021, and confirmed in interview,the laboratory failed to retain all patient test records for at least 2 years for 9 of 9 patient records reviewed. Findings were: 1. Random review of the patient test logs from 2020 to 2021 revealed no documentation of the original test reports for 9 of 9 patients reviewed. 12/17/20 - patient ID 232749 12/11/20 - patient ID 232991 05/11/21 - patient ID 234495 05/11/21 - patient ID 230630 04/09/21 - patient ID 232974 05/11/21 - patient ID 234561 01/19/21 - patient ID RIDEJA0032024 01/18/21 - patient ID 230758 01/18/21 - patient ID MONRBR0013087 2. An interview with the testing person #1 on 6/4/21 at 1135 hours in the office confirmed the above findings. She acknowledged that the testing personnel discarded the printouts from the analyzer after the results are transferred onto their LIS system.
D5215	Based on review of the CMS national database, 2019 to 2021 American Proficiency Institute (API) proficiency testing records, and confirmed in interview, the laboratory failed to verify the accuracy of their hematology testing after receiving a score of an artificial 100% for 1 of 7 of the hematology proficiency testing events reviewed.

	Findings were: 1. Review of the CMS national database revealed the laboratory received "100" for all the analytes for 1 of 7 API testing events in 2019 to 2021. 2020 1st event WBC - 100% RBC - 100% HGB - 100% HCT - 100% PLT - 100% WBC Diff - 100% 2. Review of the laboratory API test records revealed the laboratory received "100" for Not Graded for the above proficiency testing event. 2020 1st event WBC - Not Graded RBC - Not Graded HGB - Not Graded HCT - Not Graded PLT - Not Graded WBC Diff - Not Graded 3. Review of the evaluation sheet for the above test event revealed "great job" on the evaluation along with the lab director's signature. 4. An interview with the facility manager on 6/4/21 at 1020 hours in the office confirmed the above findings. She confirmed that the laboratory entered lab reported test problem and did not perform the test event and no results were evaluated.
D5291	Review of the laboratory's policy, American Proficiency Institute (API) proficiency testing (PT) records from 2019 to 2021 and confirmed in interview, the laboratory failed to have quality assessment policies and procedures that can identify, monitor and correct problems in the general laboratory systems for 2 of 7 PT events reviewed. Findings were: 1. Review of the laboratory policy Quality Assurance Policies and Procedures under Proficiency Testing revealed "all proficiency test results will be reviewed and corrective actions will be taken for any failures." 2. A review of the API proficiency testing events from 2019 and 2021 revealed that on 2 of 7 events, instances when the laboratory scored less than 80% for a nonregulated analyte, there were no documentation of patient corrective action. 2021 Hematology 1st event MCV - 20% RDW - 0% 2019 Hematology 1st event MCV - 60% 3. An interview with facility manager on 6/4/21 at 1000 hours in the office confirmed the above findings.
D5400	The laboratory did not have an effective mechanism by which to monitor & evaluate the overall quality of the analytic systems, to identify & correct problems for each specialty & subspecialty of testing performed by the laboratory in the following areas: Control procedures (see D5441, D5469).
D5429	Based on review of the manufacturer's instructions, laboratory maintenance records from July 2020 to February 2021, and confirmed in interview, the laboratory failed to document the weekly and monthly maintenance on the Sysmex KX-21N hematology analyzer for 10 of 20 weeks reviewed and 1 of 6 months reviewed. Findings included: 1. Review of the Sysmex KX-21N Operator's Manual - October 1999 under maintenance and supplies replacement chapter revealed the following maintenance: "Weekly: Clean SRV Tray Monthly: Clean Waste Chamber 3-month: Clean Sample Rotor Valve" 2. Review of the maintenance logs from July 2020 to February 2021 revealed no documentation of the above maintenance for 10 of 20 weeks reviewed and 1 of 6 months reviewed. Weekly 11/6/2020 11/13/2020 11/20/2020 10/9/2020 10 /16/2020 08/13/2020 08/20/2020 07/08/2020 07/15/2020 07/24/2020 Monthly 11 /2020 3. Review of the CMS116 revealed the laboratory performed 1500 hematology tests annually. 4. An interview with the facility manager on 6/4/21 at 1010 hours in the office confirmed the above findings.
D5441	Based on a review of laboratory procedures, laboratory quality control records from 09 /2020 to 05/2021, and confirmed in interview, the laboratory failed to have a quality control procedure that monitored the accuracy and precision over time of the Sysmex KX-21N hematology analyzer for 12 of 12 quality control lots reviewed. Findings included: 1. A review of the laboratory's procedures revealed the laboratory failed to have a procedure to determine the acceptability of quality control results over time. 2. Review of the quality control records from 09/2020 to 05/2021 revealed the laboratory used the following 12 quality control lot numbers. EightCheck 3WP X-Tra lot

	11390710, exp 8/25/21 lot 11390711, exp 8/25/21 lot 11390712, exp 8/25/21 lot 10550710, exp 6/2/21 lot 10550711, exp 6/2/21 lot 10550712, exp 6/2/21 lot 03370710, ex 3/10/21 lot 03370711, ex 3/10/21 lot 03370712, ex 3/10/21 lot 02530710, ex 12/16/20 lot 02530711, ex 12/16/20 lot 02530712, ex 12/16/20 3. Review of the laboratory records from 09/2020 to 05/20201 revealed no documentation the laboratory monitored over time the accuracy and precision of test performance of the above quality controls. 4. Review of the laboratory CMS116 revealed the laboratory performed 1500 hematology tests annually. 5. An interview with the facility manager on 6/4/21 at 1000 hours in the office confirmed the above findings. **This is a repeat deficiency from 03/29/16 survey.
D5469	Based on review of the laboratory quality control records from 09/2020 to 05/2021, and confirmed in interview, the laboratory failed to verify the acceptable quality control range for 12 of 12 lots of quality control for the Sysmex KX-21 N hematology analyzer. Findings included: 1. Review of the quality control records from 09/2020 to 05/2021 revealed the laboratory used the following 12 quality control lot numbers. EightCheck 3WP X-Tra lot 11390710, exp 8/25/21 lot 11390711, exp 8/25/21 lot 11390712, exp 8/25/21 lot 10550710, exp 6/2/21 lot 10550711, exp 6/2/21 lot 10550712, exp 6/2/21 lot 03370710, ex 3/10/21 lot 03370711, ex 3/10/21 lot 03370712, ex 3/10/21 lot 02530710, ex 12/16/20 lot 02530711, ex 12/16/20 lot 02530712, ex 12/16/20 2. Review of the laboratory records from 09/2020 to 05/20201 revealed no documentation the laboratory verified the manufacturer QC acceptable ranges for the above lot numbers. 3. Review of the laboratory CMS116 revealed the laboratory performed 1500 hematology tests annually. 4. An interview with the facility manager on 6/4/21 at 1000 hours in the office confirmed the above findings. **This is a repeat deficiency from 03/29/16 survey.
D5791	Based on review of laboratory's QA (quality assurance) records and confirmed in interview, the laboratory failed to establish a QA system to monitor, assess, and correct problems in the laboratory for the analytical phase of testing. Findings included: 1. Review of the laboratory Quality Assurance Policies and Procedures under Quality Control Assessment revealed "the laboratory director reviews all quality control charts and logs on a monthly basis. 2. The laboratory failed to have a quality control procedure that monitored the accuracy and precision over time of the Sysmex KX-21N hematology analyzer for 12 of 12 quality control lots reviewed. Refer to D5441. 3. The laboratory failed to establish the acceptable quality control range for 12 of 12 lots of quality control for the Sysmex KX-21 N hematology analyzer. Refer to D5469.
D5805	Based on a random review of 9 patient charts and confirmed in interview, the laboratory failed to include the name and physical address of the laboratory on all hematology test reports. Findings were: 1. A review of patient charts revealed that on 9 of 9 patient in-house hematology test report forms reviewed, the name and the physical address of the testing facility was not on the report form. 12/17/20 - patient ID 232749 12/11/20 - patient ID 232991 05/11/21 - patient ID 234495 05/11/21 - patient ID 230630 04/09/21 - patient ID 232974 05/11/21 - patient ID 234561 01/19 /21 - patient ID RIDEJA0032024 01/18/21 - patient ID 230758 01/18/21 - patient ID MONRBR0013087 2. An interview of testing person #1 on 6/4/21 at 1140 hours in the office confirmed the above findings.
D5807	Based on review of the laboratory patient reports from December 2020 to May 2021 and confirmed in interview, the laboratory failed to document reference ranges on their patient electronic records printouts for 9 of 9 patient records reviewed. Findings

	included: 1. Review of the laboratory results for the CBC testing on the Sysmex XN hematology analyzer revealed it tested for the following 10 analytes. WBC RBC Hematocrit Hemoglobin MCV MCH MCHC Lymphs Monos Platelets 2. Random review of the laboratory results from December 2020 to May 2021 revealed 9 of 9 reports with no documentation of the reference interval for each analyte of the CBC test. 12/17/20 - patient ID 232749 12/11/20 - patient ID 232991 05/11/21 - patient ID 234495 05/11/21 - patient ID 230630 04/09/21 - patient ID 232974 05/11/21 - patient ID 234561 01/19/21 - patient ID RIDEJA0032024 01/18/21 - patient ID 230758 01/18 /21 - patient ID MONRBR0013087 3. An interview with testing person #1 on 6/4/21 at 1140 hours in the office confirmed the above findings.
D6000	Based on review of instrument verification records, review of patient final reports, and confirmed in interview, the laboratory director failed to provide overall management and direction of the laboratory. (refer to D6020)
D6020	Based on review of the laboratory quality control records and confirmed in interview, the laboratory director failed to ensure the laboratory established and maintained a quality control program in hematology. Refer to D5441, D5469