Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2128678	02/21/2020
Name of Provider or Supplier	**Street Address, City, State**	
Altru Diagnostics Inc	8566 Katy Freeway Suite 121, 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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as spe this part. This STANDARD is not met as evidenced by: Unannounced revisit performed on 2/19/20 - 2/21/20: **New Deficiency Based on a review of the lal review of the laboratory's American Proficiency Institute proficiency testing records from 2019, and s revealed that the laboratory failed to have documentation of reviewing and evaluating the proficiency 11 events in 2019. Findings include: 1. A review of the laboratory's policy titled 'Quality Assessment following: "The laboratory will participate in qualified proficiency testing programs available for eac the lab. The Medical Director will review all proficiency testing results." 2. Further review of the labo Proficiency Institute proficiency testing records from 2019 revealed the laboratory failed to have docu and evaluating the proficiency testing results for the following events: 2019 Hematology/Coagulation Immunology/Immunohematology 2nd event 3. An interview with technical consultant #1 (as indicate on 2/19/20 at 1:15 p.m. in the laboratory, after review of the records, confirmed the above findings. **********
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficien does not reflect laboratory test performance (that is, when the proficiency testing program does not ob required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for no return or results).

This STANDARD is not met as evidenced by:
An unannounced revisit was performed on 2/19/20 -2/21/20. **New Deficiency II. Based on review c
College of American Pathologists (CAP) laboratory proficiency testing (PT) records, and confirmed i
laboratory failed to verify the accuracy of the nonregulated analytes Influenza A Subtype, Parainfluer
2019. Findings were: 1. Review of the laboratory policy Proficiency Testing Policy (Ver 1) in use 7/1
and Corrective Action Response revealed "the laboratory shall investigate and take corrective actions
PT results. Review of corrective actions must be documented and kept in the laboratory for a minimu
of the CAP Actions Laboratories Should Take When PT Result is not Graded (Rev 8/2019) revealed '
identify all analytes with an exception reason code, review and document the acceptability of perform
and retain documentation of review for at least 2 years. [26] Review participant summary for compara
document performance accordingly. Evaluation criteria are not established for educational challenge.
determine their own evaluation criteria approved by their their laboratory director for self evaluation.'
the CAP proficiency testing records from 2019 revealed the following 4 of 8 events with no documen
evaluation for the analytes not graded by CAP. IDR-A 2019 Influenza A Subtype IDR-1 [26] IDR-2 [
[26] IDR-5 [26] Parainfluenza Subtype IDR-1 [26] IDR-2 [26] IDR-3 [26] IDR-4 [26] IDR-5 [26] Co
[26] IDR-2 [26] IDR-3 [26] IDR-4 [26] IDR-5 [26] IDR-B 2019 Influenza A Subtype IDR-6 [26] IDI
IDR-9 [26] IDR-10 [26] Parainfluenza Subtype IDR-6 [26] IDR-7 [26] IDR-8 [26] IDR-9 [26] IDR-1
Influenza A Subtype IDR-11 [26] IDR-12 [26] IDR-13 [26] IDR-14 [26] IDR-15 [26] Parainfluenza S
IDR-12 [26] IDR-13 [26] IDR-14 [26] IDR-15 [26] Coronavirus Strain IDR-11 [26] IDR-12 [26] IDI
IDR-15 [26] 4. An interview with the technical supervisor on 2/20/20 at 1000 hours in the break room
above findings. She stated that she and the testing personnel would review all the results for accuracy
the reviews.
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41687 Unannounced revisit performed on 2/19/20 - 2/21/20: **New deficiency I. Based on a review
American Proficiency Institute's proficiency testing evaluation records for 2019 and staff interview, it
laboratory failed to have documentation of verifying the accuracy of analytes that were not graded by
program for 3 of 3 hematology events in 2019. Findings include: 1. A review of the American Profici
Proficiency Testing Performance Evaluation' form revealed the following: "Laboratories should revie
Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories a
documenting and performing corrective action for failures and must perform a self-evaluation using s
Participant Data Summary for samples that have not been graded." 2. A review of the laboratory's An
Institute proficiency testing evaluation records for hematology testing (Hematology/Coagulation ever
revealed the following analytes were scored as not graded: a) 2019 Hematology/Coagulation - 1st Ev
Eosinophil DIF-01 Lymphocyte DIF-01 Monocyte DIF-01 Neutrophil DIF-01 Blood Cell ID ECI-01
Blood Cell ID ECI-03 Blood Cell ID ECI-04 Blood Cell ID ECI-05 Nucleated RBCs COU-02 b) 201
/Coagulation- 2nd Event Lymphocyte DIF-02 Monocyte DIF-02 Neutrophil DIF-02 Blood Cell ID E
ECI-07 Blood Cell ID ECI-08 Blood Cell ID ECI-09 Blood Cell ID ECI-10 Nucleated RBCs COU-0
/Coagulation- 3rd Event Basophil DIF-03 Eosinophil DIF-03 Immature Cell DIF-03 Lymphocyte DI
reactive DIF-03 Monocyte DIF-03 Neutrophil, segmented DIF-03 NRBC/100 WBC DIF-03 Unclassi
Cell ID ECI-11 Blood Cell ID ECI-12 Blood Cell ID ECI-13 Blood Cell ID ECI-14 Blood Cell ID E
COU-12 3. An interview with technical consultant #1 (as indicated on the CMS 209 form) on 2/19/20
laboratory revealed the laboratory failed to have documentation verifying the accuracy of the above a
as not graded by the proficiency testing program. This confirmed the above findings. Key: NRBC= N
WBC= White blood cells RBC= Red blood cells
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D5415 TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appr
to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storag
Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Unannounced revisit performed on 2/19/20 - 2/21/20: **New deficiency I. Based on surveyor observa currently in use for the Beckman Coulter DxH 600 hematology analyzer, a review of the manufacture interview, it was revealed the laboratory failed to document the open dates and revised expiration dat Beckman Coulter DxH 600 hematology analyzer. Findings include: 1. Surveyor observation of the lal 10:00 a.m. in the laboratory revealed the following reagents currently in use on the Beckman Coulter analyzer (serial number BB51913): 2 bottles of Coulter DxH Diluent Lot number: 3527260 No open expiration date 1 bottle of Coulter DxH Cleaner Lot number: 3913020 No open date No revised expir Coulter DxH Diff Pack Lot number: 3611400 No open date No revised expiration date 1 bottle of Co Lot number: 3711180 No open date No revised expiration date 1 bottle of Coulter DxH CBC Lyse Lo open date No revised expiration date 2. A review of the manufacturer's instructions for the Beckman analyzer indicated the following Open Expiration Days for the following reagents: Coulter DxH Dilu days Coulter DxH Cleaner- open expiration 90 days Coulter DxH Diff Pack- open expiration 60 days Pack- open expiration 60 days Coulter DxH CBC Lyse- open expiration 60 days 3. An interview with (as indicated on the CMS 209 form) on 2/21/20 at 10:05 a.m. in the laboratory revealed that the labor reagent so quickly that they do not write the open date or revised expiration on the reagent boxes. Thi findings. Unannounced revisit performed on 2/19/20 - 2/21/20: **New Deficiency II. Based on revie instructions for the Beckman Coulter ES Cell Controls, surveyor observation of the quality control m interview, it was revealed the laboratory failed to have a mechanism in place to ensure QC was not ut times within 16 days, according to the Beckman Coulter manufacturer's instructions. Findings include manufacturer's instructions for the Beckman Coulter ES Cell Controls under the Table of Expected R that the Instructions for Use section of the package insert is performed a maximum of 18 times within observation on 2/20/20 at 12:30 p.m. in the laboratory revealed the following lot numbers of Beckma Controls in use: Level 1 lot number: 123172980 expiration: 2/22/20 opened: 2/17/20 Level 2 lot numb expiration: 2/22/20 opened: 2/17/20 Level 3 lot number: 143192980 expiration: 2/23/20 opened 2/17/ was asked to provide documentation of ensuring the QC was not used in excess of 18 times within 16 did not have a mechanism to document the number of uses. 4. An interview with technical consultant CMS 209 form) on 2/20/20 at 3:00 p.m. in the laboratory revealed "the quality control is good for 30 technical consultant #1 the manufacturer's instructions for the controls, it was confirmed that the labo mechanism in place to ensure QC was not utilized in excess of 18 times within 16 days.
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D5783 CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of th (2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria patient test results obtained in the unacceptable test run and since the last acceptable test run must be if patient test results have been adversely affected. The laboratory must take the corrective action nec reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
An unannounced revisit was performed on 2/19/20 -2/21/20. *** New Deficiency Based on a review logs, quality control records, patient test records, and confirmed in interview, the laboratory failed to all patient test results obtained in the unacceptable test run and since the last acceptable test run when for the AU680 chemistry analyzer. Findings were: 1. Random review of the laboratory quality contro /2019 revealed the following corrective actions for the following quality control with the following co Multiqual level 1 6/6/19 ALP lab result 21 - changed reagent, recalibrated Multiqual Level 3 12/21/19 recalibrated and repeated Streck QC 1 10/10/19 A1c lab result 4.65 - recalibrated and QC repeated 2. patient test logs from 6/5/19 revealed the laboratory performed ALP testing. Accession # 190605BM0 190605BM0018 3. Random review of the patient test logs from 12/20/19 revealed the laboratory perf

	Accession # 191220BM0002 191220BM0004 191220BM0032 4. Random review of the patient test l revealed the laboratory performed A1c testing. Accession # 191009BM0001 191009BM0008 191009 the laboratory records for the above dates revealed no documentation of the patient evaluation since t quality control run (the previous day) to include the above patients. 6. An interview with the technica /20 at 1440 hours in the break room hallway confirmed the above findings. He was unaware the labor evaluate patient test results since the last acceptable QC run. **********
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.141 provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: An unannounced revisit was performed on 2/19/20 -2/21/20 Based on review of laboratory's policy, p manufacturer's instructions, verification studies, and corrective action, the technical consultant failed oversight, as evidenced by: 1. The technical consultant failed to provide technical and scientific overs complexity preanalytic systems. Refer to D6036. 2. The technical consultant failed to ensure verificat were completed. Refer to D6040. 3. The technical consultant failed to ensure that the quality control p established and maintained for chemistry testing. Refer to D6042. 4. The technical consultant failed t problems and ensure remedial actions were taken when their test system deviated from the laboratory performance specifications. Refer to D6043.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: An unannounced revisit was performed on 2/19/20 -2/21/20 Based on review of the manufacturer's in shipping temperature studies, laboratory's shipping instructions, surveyor observation of specimens re and patient records, the technical consultant failed to provide technical and scientific oversight for mo preanalytic systems. Refer to D5311-C,D,F.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring tha taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: An unannounced revisit was performed on 2/19/20 -2/21/20 ***New deficiency Based on review of c corrective action, and patient records, the technical consultant failed to resolve technical problems an actions were taken when their test system deviated from the laboratory's established performance spe laboratory failed to have documentation of performing corrective actions on patient samples after the control run and before a failed quality control run. Refer to D5783.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing perso
the staff maintain their competency to perform test procedures and report test results promptly, accura

This STANDARD is not met as evidenced by:
An unannounced revisit was performed on 2/19/20 -2/21/20. ** New deficiency Based on review of t
laboratory personnel records, and confirmed in interview, the technical consultant failed to document
assessments for 3 of 7 personnel performing moderately complex testing in the laboratory in 2018 an
1. Review of the laboratory policy Competency Assessment Policy (GENLAB1.1) with an approved
"employee competency must be assessed at six months and one year. Competency is assessed annuall
Additionally, any time a method or instrument changes, employee competency will be assessed prior
Review of the CMS209 revealed the laboratory had 3 of 7 personnel who performed blood specimen
supervisor #2 (hire date 3/1/18) Testing person #5 (hire date 11/28/18) Testing person #7 (hire date 1/
laboratory personnel records revealed no documentation the technical consultant #2 performed the co
for the general supervisor #2 as a testing person for all moderately complex testing in 2018. An interv
supervisor on 2/20/20 at 1320 hours in the break room hallway confirmed that the TC #2 performed t
assessment but in the sister laboratory, not the current laboratory. No other competency for 2018 was
Review of the personnel records revealed no documentation of the 2019 accuracy assessments for 3 o
#5, TP#7) who performed the moderately complex blood specimen testing. 5. An interview with the g
2/20/20 at 1330 hours in the break room hallway confirmed the above findings. He was unaware the
performed on site and twice in the first year and annually thereafter.
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