Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2235380	01/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Mjsg Dba Mms Clinical Labs	11251 Richmond Ave Ste 107, 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
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: An unannounced revisit was performed on 01/11/2023. New deficiency cited I. Based on review of the laboratory's policies, stability studies, patient test records from November 2022 to January 2023, and confirmed in interview, the laboratory quality assurance failed to identify and correct problems in the preanalytic systems for two of two specimen types (nasopharangeal swabs and Urine specimens). A. nasopharangeal swabs for Flu A, Flu B, and Covid-19 B. Urine specimens for UTI panel Findings included: A. nasopharangeal swabs for Flu A, Flu B, and Covid-19 1. Review of the laboratory policy Covid Specimen Collection and Processing stated "specimen can be stored at room temperature for up to 24 hours or between 4 and 8 degrees Celsius for up to 48 hours after collection and before sample processing." 2. Review of the laboratory policy Laboratory Stability Study Procedure (effective 11/17/2022) stated an "acceptability criteria for this study is >90% recovery." 2. Review of the laboratory stability studies for nasopharangeal specimens had failures for day 3 at 2-8C (refrigerated) for sample #2, #3, and #6. sample #2 (refrigerated) Day 0 = Positive Covid-19 ; Day 3 = Negative Covid-19 sample #3 (refrigerated) Day 0 = Positive Flu B; Day 3 = Negative FluB sample #6 (refrigerated) Day 0 = Positive Covid-19 ; Day 3 = Negative Covid-19 3. Review of the stabilities revealed no documentation of repeats of the above specimens, nor any documentation of 90% recovery for the nasopharangeal swabs at 48 hours at 4-8C per the laboratory policy. 4. Review of the CMS116 signed by the laboratory owner on 10/19/2022 stated the laboratory performed 3000 Microbiology tests annually. B. Urine specimens for UTI panel 5. Review of the laboratory policy Urine Specimen Collection, Transportation, Storage

and Processing (effective date 11/17/2022) stated "specimen can be stored at room temperature, between 15 and 25 degrees Celsius, for up to 24 hours or between 4 and 8 degrees Celsius for up to 48 hours after collection and before sample processing." 6. Review of the laboratory policy Laboratory Stability Study Procedure (effective 11/17 /2022) stated an "acceptability criteria for this study is >90% recovery." 7. Review of the laboratory stability studies for urine specimens included positive samples for 2 of 15 organisms (Escherichia coli; Staphylococcus sapropyticus). No positive stability studies were available for review for the following 13 organisms: Enterobacter cloacae, Providencia stuartii, Klebsiella pneumoniae, Klebsiella oxytoca, Morganella morganii, Klebsiella aerogenes, Enterococcus faecalis, Citrobacter freundii, Proteus vulgaris, Candida albicans, Streptococcus agalactiae, Acinetobacter baumannii, Pseudomonas aeruginosa. 8. Further review of the studies stated failures for room temp on day 1 for the following samples and corresponding organisms: Enterococcus faecalis sample 2 Klebsiella pneumoniae sample 3 Klebsiella aerogenes sample 3 Enterococcus faecalis sample 3 9. Review of the stabilities did not include repeats of the above specimens, nor any documentation of 90% recovery for the urine specimens at room temperature on day 1 per the laboratory policy. 10. Review of the CMS116 signed by the laboratory owner on 10/19/2022 stated the laboratory performed 3000 Microbiology tests annually. 11. An interview with the technical supervisor on 01/11 /2023 at 1410 hours in the break room confirmed the above findings. She acknowledged that stability should include positive specimens for urines and that all specimens are transported to the laboratory at room temperature. II. Based on review of the laboratory policies, patient test records from November 2022 to January 2023. and confirmed in interview, the laboratory failed to follow its quality assurance policy and reject specimens per their specimen acceptance criteria for ten of thirty nasopharangeal swabs and two of twenty urine specimens reviewed. A. nasopharangeal swabs for Flu A, Flu B, and Covid-19 B. Urine specimens for UTI panel Findings included: A. nasopharangeal swabs for Flu A, Flu B, and Covid-19 1. Review of the laboratory policy Covid Specimen Collection and Processing stated "specimen can be stored at room temperature for up to 24 hours or between 4 and 8 degrees Celsius for up to 48 hours after collection and before sample processing." 2. Review of the laboratory policy under Specimen Rejection Criteria stated "specimens that have exceeded acceptable time frames for processing and storage." 3. Random review of the laboratory test records from November 2022 to January 2023 indicated the laboratory performed the following tests for Flu A, Flu B, and Covid-19 with a collection date after 24 hours received at room temperature. Patient ID2211270002; collected 11/25/2022; received 11/27/2022 at room temperature; elapsed time 48 hours Patient ID2211270042; collected 11/25/2022; received 11/27/2022 at room temperature; elapsed time 48 hours Patient ID2301040010; collected 01/02/2023; received 01/04/2023 at room temperature; elapsed time 48 hours Patient ID2301040017; collected 01/02/2023; received 01/04/2023 at room temperature; elapsed time 48 hours Patient ID2301040017; collected 01/02/2023; received 01/04 /2023 at room temperature; elapsed time 48 hours 4. Review of the laboratory records confirmed the laboratory reported the results for the above five nasopharangeal specimens. 5. Random review of the laboratory test records from November 2022 to January 2023 indicated the laboratory received nasopharangeal swabs for two of twenty days outside of the acceptable range of 15-25C. 11/23/2022 AFC Katy swabs at 11.2C Patient ID2211130001, Patient ID2211130021 11/14/2022 AFC Katy swabs at 11.4C Patient ID1114003, Patient ID11140004, Patient ID2211140005 6. Review of the laboratory records confirmed the laboratory reported the results for the above five nasopharangeal specimens. B. Urine specimens for UTI panel 7. Review of the laboratory policy Urine Specimen Collection, Transportation, Storage and Processing (effective date 11/17/2022) stated "specimen can be stored at room temperature,

	between 15 and 25 degrees Celsius, for up to 24 hours or between 4 and 8 degrees Celsius for up to 48 hours after collection and before sample processing." 8. Review of the laboratory policy under Specimen Rejection Criteria stated "specimens that have exceeded acceptable time frames for processing and storage." 9. Random review of the laboratory test records from November 2022 to January 2023 indicated the laboratory performed the following two of twenty urine specimens for the UTI panel with a collection date after 24 hours received at room temperature. Patient ID2211270101; collected 11/25/2022; received 11/27/2022 at room temperature; elapsed time 48 hours Patient ID2211270102; collected 11/25/2022; received 11/27 /2022 at room temperature; elapsed time 48 hours 10. Review of the laboratory records confirmed the laboratory reported the results for the above two urine specimens. 11. An interview with the technical supervisor on 1/11/2023 at 1410 hours in the break room confirmed the above findings. key: UTI panel: Urinary Tract Infection organisms Escherichia coli; Staphylococcus sapropyticus; Enterobacter cloacae, Providencia stuartii, Klebsiella pneumoniae, Klebsiella oxytoca, Morganella morganii, Klebsiella aerogenes, Enterococcus faecalis, Citrobacter freundii, Proteus vulgaris, Candida albicans, Streptococcus agalactiae, Acinetobacter baumannii, Pseudomonas aeruginosa.