Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0685116	(X3) Date Survey Completed 02/04/2020
Name of Provider or Supplier Kelsey-Seybold Clinic Memorial Villages	**Street Address, City, State** 9110 Katy Freeway, 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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory records and confirmed in interview, the laboratory failed to document the competency for 1 of 2 technical supervisor, 1 of 1 general supervisor, or 8 of 9 technical consultants. Findings were: 1. Review of the CMS209 signed 2/4/2020 by the laboratory director revealed 2 technical supervisors and 1 general supervisors. 2. Review of the laboratory personnel records revealed no documentation of the technical supervisor competency for 1 of 2 technical supervisors (TS #2, hire date 9/8/2015), 1 of 1 general supervisor (hire date 9/8/2015) or 8 of 9 technical consultants (TC #2, hire date 9/8/2015; TC#3, hire date 2/21/05; TC#4, hire date 8/25/03; TC#5, hire date 8/19/19; TC#6, hire date 11/03/03; TC#7, hire date 7/9 /07; TC#8, hire date 12/02/02; TC#9, hire date 8/25/03). 3. Review of the laboratory records revealed no documentation of a policy for assessing the competency for a technical supervisor, general supervisor nor a technical consultant. 4. An interview with the laboratory director on 2/4/2020 at 1040 hours in the conference room confirmed the above findings. He was unaware the laboratory was required to assess the competency of the above personnel.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: A. Based on review of laboratory records and confirmed in interview, the laboratory failed to verify, at least twice annually, the accuracy of all immunohistochemical and special stain tests. Findings were: 1. Random review of patient test records from 2018 to 2019 revealed the laboratory performed the professional component for the following stains: CD23 stain CD10 stain CD30 stain ALK-1 EBER PAS stain GMS 2. No documentation was available for review for the accuracy assessment for the above special stains, nor any special stains, the laboratory performed for the years 2018 and 2019. 3. An interview with the lab director on 2/4/2020 at 1100 hours in the conference room confirmed they do not perform an accuracy assessment twice a year for any special stains. He acknowledged that since he performed hundreds of special stains, it would be difficult to find another pathologist to perform the twice annual accuracy assessments. Furthermore, he was unaware that the laboratory was required to have accuracy assessment since the laboratory didn't do the "technical" component of the stains. Key GMS - Grocott-Gomori's (or Gmri) methenamine silver stain PAS - Periodic acid-Schiff EBER - Epstein-Barr Early RNA ISH (in situ hybridization) stain ALK-1 -Anaplastic lymphoma kinase (ALK 1) staining CD10- Common Acute Lymphocytic Leukemia Antigen (CALLA) CD30 - anaplastic large cell lymphoma CD23 - Fc epsilon RII, or FceRII, is the "low-affinity" receptor for IgE, an antibody isotype involved in allergy and resistance to parasites B. Based on review of the laboratory records and confirmed in interview, the laboratory failed to document twice annually the accuracy of the KOH and wet mount tests for 2018 and 2019. Findings were: 1. Review of the laboratory CMS 116 signed on 2/4/2020 revealed the laboratory performed 400 PPM testing annually. 2. Review of the laboratory records revealed no documentation of the twice annual accuracy assessment for KOH and wet mount for this laboratory for 2018 and 2019. 3. An interview with the facility manager on 2/4/2020 at 1100 hours in the conference room confirmed the above findings. She provided documentation of an online "proficiency" record for KOH and wet mounts. She stated that each provider performed the online assessment annually, but that it is used as their assessment for all laboratories for all facilities, not just this laboratory. She was unaware the laboratory must document twice annual accuracy assessment for all tests for EACH laboratory.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: A. Based on review of laboratory patient result, laboratory quality control records, and

	confirmed in interview, the laboratory failed to document the stain quality of known positive and negative reactivity with each patient slide or group of patient slides when assessing the professional component of all the immunohistochemical stains. Findings were: 1. Random review of patient test records from 2018 to 2019 revealed 1 of 18 test reports with professional interpretation for the following stains: Acct # 42039490 (2/4/19) CD23 stain CD10 stain CD30 stain ALK-1 EBER PAS stain GMS 2. Review of the quality control records for the above date revealed no documentation of the stain quality of known positive and negative reactivity of the above stains. 3. An interview of the laboratory consultant on 2/4/20 1205 hours in the conference room confirmed the above findings. He stated that he simply marks 1 checkmark for all immunohistochemical and special stains, but that it doesn't differentiate which control or which stain it referred to. B. Based on review of laboratory patient results, laboratory quality control records, and confirmed in interview, the laboratory failed to document the stain quality of known reactivity with each patient slide or group of patient slides when assessing the professional component for all special stains. Findings were: 1. Random review of patient test records from 2018 to 2019 revealed 1 of 18 test reports with professional interpretation for the following special stains: Acct # 42039490 (2/4/19) PAS stain GMS 2. Review of the quality control records for the above date revealed no documentation of the stain quality of known reactivity of the above stains. 3. An interview of the laboratory consultant on 2/4/20 1205 hours in the conference room confirmed the above findings. He stated that he simply marks 1 checkmark for all special stains, but that it doesn't differentiate which control or which stain it referred to. key: PAS - Periodic Acid Schiff stain GMS - Gomori Methenamine-Silver Nitrate Stain C. Based on a review of laboratory patient test reports and confirmed in interview, the laboratory failed to document the positive and negative control AFB (acid fast bacilli) staining QC (quality control) each day when assessing the professional component for AFB stain. Findings were: 1. Random review of patient test records from 2018 to 2019 revealed 1 of 18 patient records where the laboratory performed the professional component for AFB stain. Acct: 42039490, Date 2/04/19 Acid Fast Stain: negative 2. Review of the laboratory quality control records for the above date revealed no documentation of the positive and negatvie AFB QC. 3. An interview with the laboratory director on 2/4/2020 at 1120 hours in the conference room confirmed the above findings. He stated that he performs about 100 Acid Fast Stains annually. D. Based on a review of laboratory patient test reports and confirmed in interview, the laboratory failed to document the positive and negative control Gram Stain (GS) QC (quality control) each day when assessing the professional component for GS stain. Findings were: 1. Random review of patient test records from 2018 to 2019 revealed 1 of 18 patient records when the laboratory performed the professional component for GS stain. Acct: 42039490, Date 2/04/19 Gram Stain: negative 2. Review of the laboratory quality control records for the above date (or the week of 2/04/19) revealed no documentation of the positive and negatvie GS QC. 3. An interview with the laboratory director on 2/4/2020 at 1120 hours in the conference room confirmed the above findings. He stated that he performs about 100 Gram Stains annually.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units

	of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and confirmed in interview, the laboratory failed to document the name and address of the testing facility where the MOHS test were performed. Findings were: 1. A random review of the patient reports from January 2020 and February 2020 revealed 4 of 4 test reports with no documentation of the name and address of the testing facility where the MOHS test was performed. Date Accession # 2/3/20 20-034-173 2/3/20 20-016-77 1/14/20 20-014-55 1/20/20 20-020-088 2. An interview with the laboratory director on 2/4/20 at 1200 hours in the conference room confirmed the above findings. He acknowledged that the reports should be updated to reflect the laboratory that performed the MOHS.
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: Review of quality control records and interview of facility personnel, the laboratory director failed to ensure that the quality control program was established and maintained for histopathology. Refer to D5601