Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2087778	06/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Madhu K Kris Md Inc	750 W Olive Ave, Ste 106, Merced, CA	

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
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: Based on review of 2020-2022 laboratory records, the lack of staining quality records for 5 out of 12 cases, and interview with a laboratory person, it was determined that the laboratory failed to document the quality of stains used. Findings included: 1. Review of seven laboratory pathology reports from 2020 - 2022 revealed the practice of the laboratory to record, and thus document, the quality of stains in the "Microscopic Description" of each individual report. 2. Review of five laboratory reports from 2020 - 2022 revealed no statements documenting the quality of stains used: Date reported Case # ---------- 9/17/20 20KRI-0413 7 /14/21 21KRI-0417 7/14/21 21KRI-0418 10/17/21 21KRI-0638 5/09/22 22KRI-0280 3. A laboratory person affirmed (6/06/22 at 3:30PM) there were no other records at this laboratory for testing persons to document the quality of stains reported. 4. The reliability and quality of results reported could not be assured in the absence of stain quality records. The laboratory reported 2,775 cases 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 laboratory pathology reports selected randomly from 2020-2022, observation of the laboratory facility, and interview with a laboratory person, it was determined that the reports failed to indicate the name, address, and laboratory director of the laboratory performing Grossing. Findings included: . 1. Twelve out of 12 pathology reports described the biopsies by the number of fragments, color, and dimensions in the Gross Description, a high complexity test. 2. The laboratory was observed to be lacking the equipment and facility needed to perform grossing onsite. 3. The laboratory person affirmed (6/06/22 at 3:30PM) that grossing was not performed at this address. 4. All 12 pathology reports ommitted the name, address, and laboratory director of the laboratory issuing grossing results. a) California Business & Professions Code/BPC 1288 requires reports of results issued from another clinical laboratory to clearly show the name and address of the laboratory and the name of the laboratory director.