Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2287780	02/21/2025
Name of Provider or Supplier	**Street Address, City, State**	
Hnq Consulting Inc	3725 Glenview Rd, Glenview, IL	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the lab director (LD), the laboratory's procedure "HNQ Consulting Inc. SOP Pathology Slide Receipt, Retention and Return, Ordering Stains and Reporting" failed to include the required elements for histopathology testing affecting 2,104 tests. Findings include: 1. Review of the "HNQ Consulting Inc. SOP Pathology Slide Receipt, Retention and Return, Ordering Stains and Reporting" procedure manual and lack of documentation revealed the laboratory failed to include the following required

	elements for Hematoxylin and Eosin differential staining (H & E), special stains (Periodic acid-Schiff (PAS), Giemsa, Iron, Congo Red, Reticulin), and immunohistochemistry (IHC) stains (CD34, CD117 (C-KIT), E-Cadherin, MPO, CD61, CD3, CD20, CD138, MUM1, Kappa ISH, Lambda ISH, and PAX-5): a) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection; b) Microscopic examination, including the detection of inadequately prepared slides; c) Step-by-step performance of the procedure, including test calculations and interpretation of results; d) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing; e) The reportable range for test results for the test system as established or verified; f) Control procedures; g) Limitations in the test methodology, including interfering substances; h) Reference intervals (normal values); i) Pertinent literature references; j) Description of the course of action to take if a test system becomes inoperable. 2. Review of laboratory records revealed 2,104 patient tests performed from August 2023 to February 2025 for H & E, special stains and IHC staining. 3. On 02/21/2025, at 12:30 p.m., the LD confirmed the SOP did not contain all of the requirements for histopathology testing.
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. This STANDARD is not met as evidenced by: A Based on review of laboratory records, lack of documentation and interview with the lab director (LD), the laboratory failed to document the known reactivity of the control slides for five of five dates of patient testing of histopathology differential Hematoxylin and Eosin (H & E) and special stains (Periodic acid-Schiff (PAS), Giemsa, Iron, Congo Red and Reticulin) in 2023, 2024 and 2025. Findings include: 1. Review of patient test reports revealed differential / special stain testing performed on the following dates: a) DATE: 11/16/2023 MRN: P23-06649 DIFFERENTIAL / SPECIAL STAINS: H & E, PAS, Giemsa, Iron and Reticulin b) DATE: 12/13/2023 MRN: P23-07271 DIFFERENTIAL / SPECIAL STAINS: H & E, PAS, Giemsa, Iron and Reticulin c) DATE: 09/11/2024 MRN: P24-07644 DIFFERENTIAL / SPECIAL STAINS: H & E, PAS, Giemsa, Iron and Congo Red d) DATE: 10/01/2024 MRN: P24-08175 DIFFERENTIAL / SPECIAL STAINS: H & E, PAS, Giemsa, Iron and Reticulin e) DATE: 02/21/2025 MRN: P25-01187 DIFFERENTIAL / SPECIAL STAINS: H & E, PAS, Giemsa, Iron and Reticulin 2. Review of laboratory records and lack of documentation revealed the laboratory failed to document the known reactivity of differential and special stain control slides for the dates listed in Finding 1. 3. Review of laboratory records revealed 1,128 differential and special stains tested from September 2023 to February 2025. 4. On 02/21/2025, at 10:13 a.m., the LD confirmed the known reactivity of the differential and special stain control slides was not recorded. B Based on review of laboratory records, lack of documentation and interview with the lab director (LD), the laboratory failed to document the positive and negative reactivity for each time of use for histopathology immunohistochemistry (IHC) stains (CD34, CD117 (C-KIT), E-Cadherin, MPO, CD61, CD3, CD20, CD138,

	MUM1, Kappa ISH, Lambda ISH, and PAX-5) for five of five patients reviewed in 2023, 2024 and 2025. Findings include: 1. Review of patient test reports revealed IHC staining performed on the following dates: a) DATE: 11/16/2023 MRN: P23-06649 IHC STAINS: CD34, CD117 (C-KIT), E-Cadherin, MPO b) DATE: 12/13/2023 MRN: P23-07271 IHC STAINS: CD34, CD61, CD3, CD20 c) DATE: 09/11/2024 MRN: P24-07644 IHC STAINS: CD138, MUM1, Kappa ISH, Lambda ISH, CD3, CD20, PAX-5, CD34, CD117 (C-KIT), MPO, E-Cadherin d) DATE: 10/01/2024 MRN: P24-08175 IHC STAINS: CD34, CD117 (C-KIT), CD61, CD3, CD20, PAX-5, CD138, MUM1, Kappa ISH, Lambda ISH e) DATE: 02/21/2025 MRN: P25-01187 IHC STAINS: CD34, CD3, CD20, PAX-5 2. Review of laboratory records and lack of documentation revealed the laboratory failed to document the positive and negative reactivity for all IHC stains performed for five of five patients listed in Finding 1. 3. Review of laboratory records revealed 976 IHC stains tested from September 2023 to February 2025. 4. On 02/21/2025, at 10:13 a.m., the LD confirmed the positive and negative reactivity for IHC stains was not recorded with each time of use.