| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 36D0929864 | 10/10/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Glickman Urological & Kidney | 1330 Mercy Drive Nw, Suite 510, Canton, OH | |

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 |
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| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based upon a review of lab policies, test accuracy verification records and an interview with the Laboratory Director (LD), the laboratory failed to perform test accuracy verification twice annually. Findings were as follows: 1. The surveyor was presented with a binder titled "Urology One Standard Operating Procedure Manual". The binder contained a document titled " Policy: Quality Assessment/Peer Review" which revealed the following statement: "2. Individual pathologists will be evaluated through a review processing the Proficiency section of the SOP. This includes second opinions where the diagnosis isn't shared and peer review. This will include a minimum of 16 cases per year." 2. The surveyor requested test accuracy verification records for 2017 and 2018. A document titled "PT Blind review" was provided which contained 9 selected cases for accuracy assessment which were forwarded to P4 Diagnostix for peer review. Nine cases selected: 20195 18025 20944 01490 02388 00250 16888 16887 17006 2. The "PT Blind review" sheet did not contain any dates of submission, only 3 peer review signatures without dates, and no LD review and date. The laboratory director verified no dates for peer review had been documented during 2017 and 2018. The interview occurred on 10/10/2018 at 2:00 PM. |
| **D5293** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(b)(c)<br><br>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general |

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| | laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on procedure review and an interview with Laboratory Director (LD), the laboratory failed to review and document the effectiveness of their quality assessment program of the general laboratory systems. Findings were as follows: 1. Review of the laboratory's "Standard Report Review CLIN-008-04" policy and procedure, provided on the date of the inspection, found the following statement: "Responsibility: ... Managerial staff is responsible for the review departmental reports/records related to Laboratory performance specific to their assigned area of responsibility." 2. The surveyor requested documentation of the reviews for 2017-2018 which the laboratory was unable to provide. 3. The LD confirmed the laboratory did not document any report reviews for quality assessment in 2017-2018. The interview occurred on 10/10 /2018 at 2:30 PM. |
| **D5779** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(a)<br><br>Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policies and procedures, review of test accuracy verification records, and an interview with the Laboratory Director (LD), the laboratory failed to have and follow a corrective action policy and procedure to ensure accurate and reliable patient test results and reports. Findings Include: 1. Review of the laboratory's policy and procedure binder titled " Urology One Standard Operating Procedure Manual", provided on the date of survey, did not find any mention of a policy and procedure for the test accuracy verification, to include corrective action protocols when a discrepancy of diagnosis occurs. 3. The Surveyor requested the laboratory's corrective action policy and procedure for the 2017-2018 test accuracy verification The LD confirmed the laboratory does not have a corrective action policy and procedure established, and was unable to provide the requested documentation on the date of survey. The interviews occurred on 10/10/2018 at 2:00 PM. |
| **D5893** | POSTANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1299(b)(c)<br><br>(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and an interview with the Laboratory Director (LD), the Laboratory Director failed to ensure that a post analytic quality assessment program was maintained to assure the quality of laboratory services provided and to identify |

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| | failures in quality. Findings Include: 1. Review of the laboratory's "Urology One Standard Operating Procedure Manual" revealed a "Policy: Quality Assurance" procedure which contained the following statements: "1. ...An annual quality assurance report will be prepared by the Manager in collaboration with the representative from Theranostix, supervised and approved by lab director and presented at this meeting. All quality measures will be discussed." "3. ...At month end a review of random 10% cases is performed and documented for compliance." "5. Results of competency assessment (performed twice annually as per procedure) will be summarized and reported on the end of the year quality assurance meeting, and summarized in the annual quality assurance report." 2. The surveyor requested the annual quality assurance report for review. The LD was unable to provide the annual quality assurance report. 3. The surveyor requested documentation of the 10% of random cases pulled for compliance for 2017 and 2018. The LD was unable to provide the documentation of cases. The interview occurred on 10/10/2018 at 2:50 PM. |
| **D6106** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(14)<br><br>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policy and procedure manual and an interview with the Laboratory Director (LD), the Laboratory Director failed to ensure that approved policies and procedures were available to all personnel responsible for any aspect of the testing process. Findings Include: 1. Review of the laboratory's "Urology One Standard Operating Procedure Manual", did not find any indication that the Laboratory Director approved the policies and procedures prior to the implementation of patient testing in 2016, 2017 and 2018, via a signature and date. 2. The Surveyor requested the laboratory's approved policies and procedures from the Laboratory Director. The Laboratory Director confirmed the Laboratory Director did not indicate approval on all of the policies and procedures via a signature and date prior to the implementation of patient testing and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 10/10/2018 at 2:20 PM. |