Mecklenburg County
Department of Internal Audit

Department of Public Health
Clinical Laboratory and Radiologic Test Results and Notifications
Report 1767

June 14, 2018

Internal Audit's Mission	To support key stakeholders in cultivating an environment of accountability, transparency, and good governance.
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MECKLENBURG COUNTY
Department of Internal Audit

To: Gibbie Harris, Director, Department of Public Health

From: Joanne Prakapas, Director, Department of Internal Audit

Date: June 14, 2018

Subject: Department of Public Health Clinical Laboratory and Radiologic Test Result Notifications Audit 1767

The Department of Internal Audit has completed its audit of the Department of Public Health Clinical Laboratory and Radiologic Test Result Notifications. The audit objective was to determine whether internal controls effectively manage key business risks inherent to test result notifications. This audit included test result notifications for Pap smears; human immunodeficiency virus (HIV) and sexually transmitted diseases (STDs); mammograms; colorectal cancer screenings; and tuberculosis (TB). The audit excluded test result notifications given to patients at the time of their visit, e.g., dental x-ray results. Internal Audit interviewed key personnel; reviewed and evaluated policies, procedures, and other documents; observed operations; and tested various activities for the period of April 1, 2014 through March 31, 2017.

This audit was conducted in conformance with The Institute of Internal Auditors' International Standards for the Professional Practice of Internal Auditing. These standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

OVERALL EVALUATION

Overall, the management of key risks inherent to clinical laboratory and radiologic test result notifications requires improvement in the design and operation of some control activities.

RISK OBSERVATION SUMMARY

The table below summarizes the risk observations identified during the audit, grouped by the associated risk factor, and defined in Appendix A. The criticality or significance of each risk factor, as well as Internal Audit's assessment of the design and operation of key controls to effectively mitigate the risks, are indicated by the color codes described in Appendix B.

RISK OBSERVATION SUMMARY			
Risk Factors and Observations	**Criticality**	**Design**	**Operation**
1. Policies and Procedures Risk	🔴	🟡	🟡
1.1 Formal Documentation			
2. Documentation Risk	🔴	🟡	🟡
2.1 Electronic Medical Records Documentation 2.2 Electronic Medical Records Data Input			
3. Compliance Risk	🔴	🔴	🟡
3.1 Communication Protocol 3.2 Quality Control and Monitoring 3.3 Notification Activities			
4. Human Resource Risk	🟡	🟡	🟡
4.1 Training			
5. Segregation of Duties Risk	🔴	🟢	🟢
No risk observations noted			

The risk observations and management's risk mitigation strategies defined in Appendix C are discussed in detail in the attached document. Internal Audit will conduct a follow-up review to verify management's action plans have been implemented and are working as expected.

We appreciate the cooperation you and your staff provided during this audit. Please feel free to contact me at 980-314-2889 if you have any questions or concerns.

c: County Manager
Assistant County Manager/Chief of Staff
Assistant County Managers
Deputy County Attorney
Senior County Attorney
Board of County Commissioners
Audit Review Committee

BACKGROUND

The public health system helps ensure all residents of the State of North Carolina have equal access to essential public health services. A local health department must provide ten essential services to county residents, such as providing public health education; monitoring, diagnosing, and identifying community health problems; working with partners in the community to identify and solve health problems; and enforcing laws and regulations that protect health and ensure safety. The local county health department director acts as the administrative head and has specific powers and duties as cited in NCGS §130A-41.

On July 1, 2013, the County transitioned public health services, previously managed under contract with Carolina Healthcare System, back to the Mecklenburg County Health Department. The Health Department has four divisions—Clinic Services, Community Health Services, Environmental Health, and Children's Developmental Services. This audit focused on the Clinic and Community Health Services divisions' test result notification processes for the following:

- Cervical cancer (Pap[1] smears)
- Human immunodeficiency virus (HIV)
- Sexually transmitted diseases (STDs)
- Hepatitis B and C[2]
- Breast cancer (mammograms)
- Colorectal cancer
- Tuberculosis (TB)

The Clinic Services Division targets the prevention and treatment of communicable diseases in the County. The majority of clinic services is operated from the southeast and northwest campuses with multiple clinics, such as Tuberculosis Control, Refugee, Sexually Transmitted Disease Control, Family Planning, Women's Health, and the Breast and Cervical Cancer Control Program (BCCCP). The Community Health Division also provides free and confidential screening for HIV and STDs through its Community-Based Testing program.

Service Vendors

The Health Department relies on several third-party vendor services in its mission to deliver health services to County residents:

North Carolina State Lab—provides the Mecklenburg County Health Department with laboratory tests to identify infections with a variety of bacterial and viral pathogens of public health significance, including but not limited to testing for the following diseases: HIV, syphilis, herpes, hepatitis B, and hepatitis C. The State Lab also provided Pap smear testing for the Health Department until January 2015, at which point LabCorp began conducting this test.

[1] Papanicolaou test

[2] Internal Audit examined test result notification processes for Hepatitis B testing performed by the Refugee Clinic and Hepatitis C testing performed by Community-Based Testing.

LabCorp—is the Health Department's lab services provider for Pap smear testing and some hepatitis C testing.

Charlotte Radiology—is the Health Department's radiology services vendor that provides screening and diagnostic mammography services to Women's Health/BCCCP Clinic patients on a referral basis. They also provide chest x-ray reading services for the County's Tuberculosis Control Clinic.

Information Systems

The Health Department utilizes multiple information systems to support the delivery of patient health services.

Cerner—is the electronic medical records patient care management system (EMR system) giving health providers a single access point to patient information, helping in patient health care activities:

- Register, schedule, and bill patients
- Obtain patient histories, provider referrals for treatment and follow-up, laboratory test specimen tracking and results, and other information
- Monitor patients' activities and follow up on their care as necessary

Each patient record is tracked in the EMR system by a unique medical record number (MRN). Patient medical information and relevant activity are entered into the EMR system. Data may be manually entered or scanned in by Health Department staff, or directly imported from third-party systems.

Televox—is an automated messaging system that allows patients to access their HIV and STD test result messages via telephone or internet.

North Carolina Electronic Disease Surveillance System (NCEDSS)—is a web-based health surveillance and reporting system provided by the Division of Public Health Communicable Disease Branch, which must be used to report communicable disease data to the State.

Patient Testing and Follow-up

Health Department medical providers may determine patients need laboratory tests or follow-up tests based on examinations or prior test results. Clinic nursing staff also uses standing orders to determine appropriate test result follow-up activities. Patients may get needed follow-up testing at the Health Department, be referred to external clinics or programs, or use their own health care providers for follow-up services. The providers either enter their review activities and instructions for patient follow-up directly into the EMR system or write this information on hard-copy documentation for subsequent scanning into the EMR system.

Specimen Analysis

Patient test specimens collected at the Health Department may be analyzed in-house or sent to an outside laboratory to be analyzed. All results are entered into the EMR system through electronic data interface or manual entry by staff, depending on the test.

Test Result Notification Process

Notification requirements vary depending upon the test type and result. For example, clinic staff do not conduct patient notifications for some normal test results. In addition, certain abnormal results may require in-person notification, while other results may be provided via letter, phone call, or automated messaged service. Further, clinic notification requirements end once a County or State Disease Intervention Specialist (DIS) is notified of a patient's abnormal HIV or syphilis test result.

HEALTH DEPARTMENT TEST RESULT NOTIFICATION REQUIREMENTS		
Clinic Service Ordered	**Positive/Abnormal Result**	**Negative/Normal Result**
Mammogram	• Two calls and certified letter if radiology vendor unable to contact patient • Notifications within 60-day timeframe to enter diagnostic and/or treatment disposition	• Radiology vendor communicates results to patient
Colorectal Cancer Screening	• Two calls and a letter • Notifications within 30 days of result receipt	• Single letter sent to patient
Tuberculosis Testing	Chest x-ray that requires additional testing • Multiple attempts to contact • No specific communication method • No specific timeframe to notify Sputum • Multiple attempts to contact • Home visit within two weeks if no prior contact • No specific communication method	• Single letter sent to patient • Notification made only if patient is under quarantine
Pap Smear (Adult Health Clinic)	• Three letters, third letter certified • Second and third letters sent within one month of prior letter	• No notification required

HEALTH DEPARTMENT TEST RESULT NOTIFICATION REQUIREMENTS		
Clinic Service Ordered	**Positive/Abnormal Result**	**Negative/Normal Result**
Pap Smear (Refugee Clinic)	• Nurse attempts to contact patient of refugee sponsor agency • No specific communication method • No specific timeframe to notify	• No notification required
STD[3] (Adult Health)	• Televox message • Two letters, second letter certified[4] • First and second letters sent within two weeks of prior notification	• Televox message
STD (Refugee)	• Nurse attempts to contact patient of refugee sponsor agency • No specific communication method • No specific timeframe to notify	• No notification required
STD[5] (Community Based Testing)	• No notification required	• No notification required
Syphilis (Adult Health)	• Televox message[6] • Two letters, second letter certified[4] • First and second letters sent within two weeks of prior notification • County or State DIS worker also contacts patient	• Televox message
Syphilis (Refugee and Tuberculosis Clinics)	• County or State DIS worker contacts patient	• No notification required
Syphilis (Community Based Testing)	• County or State DIS worker contacts patient	• No notification required

[3] Adult Health and Refugee STD testing included chlamydia, gonorrhea, and herpes.
[4] Letters not required if patient has received adequate treatment for disease.
[5] Community-based STD testing included chlamydia and gonorrhea, as well as Hepatitis C.
[6] Televox automated messaging used for HIV results notification starting May 5, 2015 and Syphilis starting September 1, 2015.

HEALTH DEPARTMENT TEST RESULT NOTIFICATION REQUIREMENTS		
Clinic Service Ordered	**Positive/Abnormal Result**	**Negative/Normal Result**
HIV (Adult Health and HIV Walk-in Clinics)	• Televox message[6] for patient to return to clinic • County or State DIS worker also contacts patient	• Televox message
HIV (Community Based Testing)	• County or State DIS worker contacts patient	• No notification required
HIV (Refugee and Tuberculosis Clinics)	• County or State DIS worker contacts patient	• No notification required
Hepatitis B (Refugee Clinic)	• County Communicable Disease worker contacts patient	• No notification required

Health Department staff may not always be able to reach patients via methods prescribed by notification policies. For example, notification letters may be returned as undeliverable due to an incorrect mailing address; the intended recipient may decline acceptance of a certified results letter; or a patient's telephone may be out of service. In addition to required notification activities, nurses and other Health Department staff may communicate patient test results by alternative means, such as inbound patient telephone calls, subsequent office visits, or via direct meetings with a patient at his or her home or in the community.

Testing Methodology

Internal Audit analyzed EMR, Televox, and LabCorp data to determine whether the Health Department communicated patient test results in accordance with State and/or County requirements. We did not test whether the patient obtained the provider-recommended services. Testing included the entire population of abnormal or unsatisfactory results for test orders placed from April 1, 2014 through March 31, 2017, except for Adult Health Clinic HIV and syphilis testing. The testing population for these tests began May 5, 2015 and September 1, 2015 respectively. Regardless of whether evidence of treatment was documented in the EMR system, an exception was noted if there was no evidence of required notifications in the EMR system or Televox (STDs).

[6] Televox automated messaging used for HIV results notification starting May 5, 2015 and Syphilis starting September 1, 2015.

COUNTY MANAGER'S OVERALL RESPONSE

The County Manager concurs with all risk mitigation strategies and timeframes for implementation.

RISK OBSERVATIONS AND MITIGATION STRATEGIES

Risk Factor	Criticality	Design	Operation
1. Policies and Procedures Risk	🔴	🟡	🟡

Risk Observation

1.1 Formal Documentation—While the Health Department had formal, documented policies and procedures for many aspects of its patient test results notification process, some procedures did not reflect current and/or best practices. For example, there was no naming standard for laboratory results, clinical notes, and other information keyed into the EMR system. Yet, policies and procedures are important control activities to help management ensure its directives are carried out while mitigating risks that may prevent the organization from achieving its objectives.

Recommendation

1.1 Internal Audit recommends management develop formal, documented policies and procedures, and train staff accordingly. Procedures should, at a minimum, include:

- Documentation standards
- Notification timeframes
- Staff roles and responsibilities, including proper segregation of duties
- Supervisory oversight and monitoring
- Training requirements
- Internal and external communication requirements

Management's Response

1.1 **Risk Mitigation Strategy:** Reduce **Implementation Date:** August 2018

Action Plan: A multidisciplinary team developed "Standardized Workflow" documents for all STD and Pap test resulting activities, emphasizing standardization and several layers of quality assurance monitoring. The Workflows include *required* step-by-step processes for result review and follow-up for patients seen in all programs that provide STD and Pap testing. The Workflows explicitly outline responsibilities of involved parties, detailed process steps, notification timeframes, documentation requirements, quality assurance process steps, and a staff training plan.

- The Pap test resulting Workflow was completed 2/27/17.
- The STD test resulting Workflow was completed 4/27/17.
- The Adult Health and Breast and Cervical Cancer Control Program policy and procedure committee was re-established on 5/23/17.

Upon the review of this Internal Audit report, it was verified by Internal Audit staff that there were no trending issues associated with follow-up notification for mammograms, colorectal screenings, and TB testing. Thus, emphasis had been placed on urgent Workflow completion for Pap and STD tests. These efforts will be duplicated for mammograms, colorectal screenings, and TB testing.

The Workflows will be completed by 8/1/18.

Additionally, Clinic Leadership will implement a formal, comprehensive policy and procedure committee for the TB/Refugee Clinic by 8/1/18.

Risk Factor	Criticality	Design	Operation
2. Documentation Risk			

Risk Observations

2.1 Electronic Medical Records Documentation—The EMR system did not always have consistent and complete information to help ensure clinical and community-based testing health services staff provide adequate patient care and management oversight.

- Community-Based Testing patient contact attempts, such as calls, were not documented in the EMR system.
- The EMR patient note subject names did not follow a standard naming convention to facilitate reporting and management oversight.
- The EMR patient note content did not contain consistent supporting documentation and notations for management to determine whether patient test result notifications occurred in accordance with State and County standards. For example, some patient notes did not contain the test name, documentation of test result, provider follow-up instructions, and/or the test result notification date.

2.2 Electronic Medical Records Data Input—Patient information was sometimes maintained outside the EMR system until later in the notification process. In addition, the EMR system did not have the available forms to facilitate Tuberculosis (TB) patient information input. Delays in EMR data entry could result in patient data being lost or unavailable to everyone that may need the information.

Hard-copy documents maintained outside of the EMR system were:

- Pap smear results report
- TB medical history and x-ray results report
- BCCCP patient information form
- Provider follow-up notification instructions for Pap smear and TB test results

Recommendations

2.1 Internal Audit recommends management develop and implement a consistent approach to entering and labeling data and supporting documentation in the EMR system, and train staff accordingly.

2.2 Internal Audit recommends management ensure staff timely enters all necessary patient information into the EMR system. In addition, management should work with the EMR system vendor to identify ways to increase its capabilities, e.g., developing required forms within the EMR system to allow staff to directly input patient information into the system.

Management's Response

2.1 **Risk Mitigation Strategy:** Reduce **Implementation Date:** August 2018

Action Plan: The Workflows mentioned above contained standardized documentation requirements for the labeling of all supporting documentation in the EMR. Each document must be labeled exactly as outlined in the Workflow; otherwise, the weekly audit report will indicate non-adherence.

Training for all clinical staff, focused on participant's foundational understanding of the EMR application and best practice functionality, was completed on 3/2/17. Training on the standardized documentation requirements has been completed for the appropriate clinical staff and appropriate implementation and documentation is being monitored weekly by supervisors and management.

2.2 **Risk Mitigation Strategy:** Reduce **Implementation Date:** August 2018

Action Plan: Each step of the notification process is clearly documented within the EMR for Pap and STD test follow-up. EMR documentation is linked to audit reporting queries that notify leadership of non-adherence on a weekly basis. Discrepancies are resolved within 24 business hours.

These efforts will be duplicated for mammograms, colorectal screening, and TB test results by 8/1/18.

Additional internal process resolutions:

- Pap, STD, and colorectal screening test results are now transmitted through the EMR and no hard copies of test results are involved in the process. The path to notification is now time and date stamped throughout each process step.
- Both mammogram and colorectal screening results implemented a new custom form in the EMR on 1/2/18 that allows real time data entry and ensures all women have received the appropriate follow-up.
- TB/Refugee Clinic created an electronic Medication Administration Record (MAR) to document daily TB medication administration directly in the EMR. The new MAR will be implemented by 7/1/18.

Work with the Vendors will include:

- A plan for paperless transmission of mammogram test results that are resulted by an outside vendor

- TB/Refugee Clinic leadership is currently working towards developing custom state required forms in the EMR. In the interim, both the TB/Refugee Clinic Program is using internal spreadsheets to track and monitor all follow-up activities and ensure patients receive their results within the specified timeframes.

Risk Factor	Criticality	Design	Operation
3. Compliance Risk	🔴	🔴	🟡

Risk Observations

3.1 Communication Protocol—There was no communication protocol between the Health Department laboratory and clinics for key aspects of the patient testing and results notification process, including but not limited to:

- Specimen receipt delays from clinic
- Lab order changes and cancellations entered by clinic staff
- Test results receipt delays from Health Department and external labs
- Provider notification from the laboratory that they received the hard copy Pap smear results

3.2 Quality Control and Monitoring—The Health Department did not have an established process for independent quality review and ongoing supervisory monitoring of all patient testing and test result notification activities, e.g., STDs, BCCCP mammograms, TB testing, and Refugee Clinic tests.

In addition, because some information was scanned rather than keyed into the EMR system, management could not generate reports necessary to monitor test results and notification activities.

3.3 Notification Activities—Staff was not always compliant with State and County requirements for patient test result notifications, based on the evidence in the EMR system. The tables below summarize the notification activity exceptions by test type. Additionally, the graphs in Appendix D trend initial notification exceptions for Pap smears and STD tests.

The population under each requirement category reflects the balance of records still requiring that notification. "Other Notification Methods" include activities such as inbound patient telephone calls, or office visits.

ADULT HEALTH PAP SMEAR TESTING						
Provider Instructions	**Requirements and Exceptions for Abnormal Results**[7]					**Total Exceptions After Other Notification Methods or Treatment**
	1st Letter Sent	2nd Letter Sent	3rd Letter Sent	3rd Letter Certified	Exceptions Subtotal	
Refer for Colposcopy	48 of 596	141 of 427	109 of 201	43 of 92	341 of 596	139 of 596
Repeat in 3-6 months	18 of 176	51 of 123	32 of 54	17 of 22	118 of 176	91 of 176
Follow-up in 1 year	7 of 255	192 of 213	13 of 16	1 of 3	213 of 255	155 of 255

ADULT HEALTH SEXUALLY TRANSMITTED DISEASES						
Test	**Requirements and Exceptions for Abnormal Results**[7]					**Total Exceptions After Other Notification Methods or Treatment**
	Televox Entry	1st Letter Sent	2nd Letter Sent	2nd Letter Certified	Exceptions Subtotal	
Chlamydia	213 of 4358	258 of 482	102 of 164	20 of 62	593 of 4358	240 of 4358
Gonorrhea	98 of 1990	101 of 223	64 of 101	12 of 37	275 of 1990	91 of 1990
Herpes	61 of 359	18 of 30	1 of 6	0 of 5	80 of 359	27 of 359
Syphilis	72 of 288	7 of 13	1 of 2	0 of 1	80 of 288	33 of 288
HIV	87 of 251	NA	NA	NA	87 of 251	9 of 251

[7] Results represent exceptions where notification activities were not observed in the EMR system within one year of Pap smear result receipt or within three months of STD test result receipt for tests ordered during the audit scope period of April 1, 2014-March 31, 2017.

Recommendations

3.1 Internal Audit recommends management implement clear communication protocols for test requests, changes, test results, and other activities between laboratories and clinics. Staff should be trained accordingly.

3.2 Internal Audit recommends management implement a process for independent quality review and ongoing supervisory monitoring of all patient testing and notification activities. Staff should be trained accordingly.

3.3 Internal Audit recommends management ensure staff consistently comply with State and County requirements for patient test result notifications and document all notification activities in the EMR system.

Management's Responses

3.1 **Risk Mitigation Strategy:** Reduce **Implementation Date:** December 2018

Action Plan: Mecklenburg County Health Department is in the process of creating a contractual relationship with Lab Corp who will provide all laboratory services for the Department. There will be occasional laboratory tests sent to the State Laboratory in Raleigh or the CDC in Atlanta when specific communicable disease testing is required. It is expected that the contract will be completed by July 1, 2018 with full implementation by December 30, 2018. Lab Corp will work with the Department to create a formal policy and procedure outlining the process for communicating and monitoring delays in test results for Pap, STD, and colorectal screening test results. All laboratory results will automatically and electronically be entered into the EMR, eliminating paper test results and the need for manual entering of test results into the EMR.

Internal process resolutions implemented as of 4/23/18:

- Delays in results from internal and external labs for Pap, STD, and colorectal screening test results are managed by the Interim Lab Manager as of 2/27/18. The Interim Lab Manager communicates result delays to all providers, the follow-up teams, and the Interim QA Coordinator via email.
- Delays in TB test results are monitored by the TB/Refugee Clinic Supervisor and follow-up nurses assigned to the specific patient. If delays occur, the follow-up nurse contacts the external lab vendor to address concerns. Logs are kept by the follow-up nurses to monitor trends in delays.
- Delay in results from our external vendor for mammogram results are directly communicated to the clinic manager and follow-up nurse.

3.2 **Risk Mitigation Strategy:** Reduce **Implementation Date:** August 2018

Action Plan: Currently, a Quality Assurance (QA) Coordinator is conducting weekly audits of Pap and STD test follow-up activities and adherence to policies procedures and Workflow documents. This work will transition to peer audits conducted by the follow-up nurses, with additional oversight by clinic leadership by 8/1/18.

The newly established Total Quality Management team will continue to collaborate with clinic leadership and the Clinical Care Model Transformation vendor to enhance monitoring systems and quality reviews, as well as conduct periodic independent monitoring. The collaborative effort aims to continue developing custom query reports for efficient, targeted audits of follow-up activities.

3.3 **Risk Mitigation Strategy:** Reduce **Implementation Date:** October 2018

Action Plan: Documentation standardization and timeframe adherence are addressed within the aforementioned Workflows. Adherence is monitored on a weekly basis. All Workflows include references to best practices, industry standards, and State and federal requirements for lab test follow-up.

Clear expectations for management's role in assuring adherence to Workflows will be clarified within Work Plans by 10/1/18.

Risk Factor	Criticality	Design	Operation
4. Human Resource Risk			

Risk Observation

4.1 Training—While the Health Department provided informal clinic-specific training, they did not have formal training to help ensure consistent staff execution of patient test result notification and documentation processes.

Recommendation

4.1 Internal Audit recommends management develop and implement formal training for patient test result notifications, documentation processes, and other relevant clinical activities.

Management's Response

4.1 **Risk Mitigation Strategy:** Reduce **Implementation Date:** August 2018

Action Plan: Providers were formally trained on new Pap test result requirements on 3/2/17. Monitoring of adherence began on 3/2/17. The Interim Pap Nurse and permanent Pap Medical Assistant (MA) were trained on 2/17/17. The permanent Pap Nurse was formally trained on 5/8/17. Providers were formally trained on new STD test result requirements on 5/19/17. STD follow-up Nurse and MA were trained on 5/22/17. Providers now use their monthly staff meetings to provide formal training on updates to the Pap and STD Workflows.

The new Workflows for mammograms, colorectal screening, and TB testing also include detailed training plans for how each staff person will be trained to complete their part of the process, as well as the dates the training will occur. Again, as Workflows are updated, the training plan is also updated to ensure all staff receive training on changes.

APPENDIX A—Risk Factor Definitions

Risk Factor	Definition
Compliance Risk	Failure to comply with established policies, procedures, and/or statutory requirements may result in unacceptable performance that impacts financial, operational, or customer objectives.
Documentation Risk	Failure to adequately collect, file, and retain key documentation may result in lack of accountability and/or evidence of inspection information and support.
Human Resource Risk	Failure to attract, train, develop, deploy, and/or empower competent personnel may inhibit the organization's ability to execute, manage, and monitor key business activities.
Policies and Procedures Risk	Failure to have formal, documented, clearly stated, and updated policies and procedures may result in poorly executed processes and/or increased operating costs.
Segregation of Duties Risk	Failure to adequately segregate duties may allow an employee or group of employees to perpetrate and conceal errors or irregularities without timely detection.

APPENDIX B—Color Code Definitions

The criticality of a risk factor represents the level of potential exposure to the organization and/or to the achievement of process-level objectives before consideration of any controls in place (inherent risk).

Criticality	Significance and Priority of Action
🔴	The inherent risk poses or could pose a significant level of exposure to the organization and/or to the achievement of process level objectives. Therefore, management should take immediate action to address risk observations related to this risk factor.
🟡	The inherent risk poses or could pose a moderate level of exposure to the organization and/or to the achievement of process level objectives. Therefore, management should take prompt action to address risk observations related to this risk factor.
🟢	The inherent risk poses or could pose a minimal level of exposure to the organization and/or to the achievement of process level objectives. Risk observations related to this risk factor, however, may provide opportunities to further reduce the risk to a more desirable level.

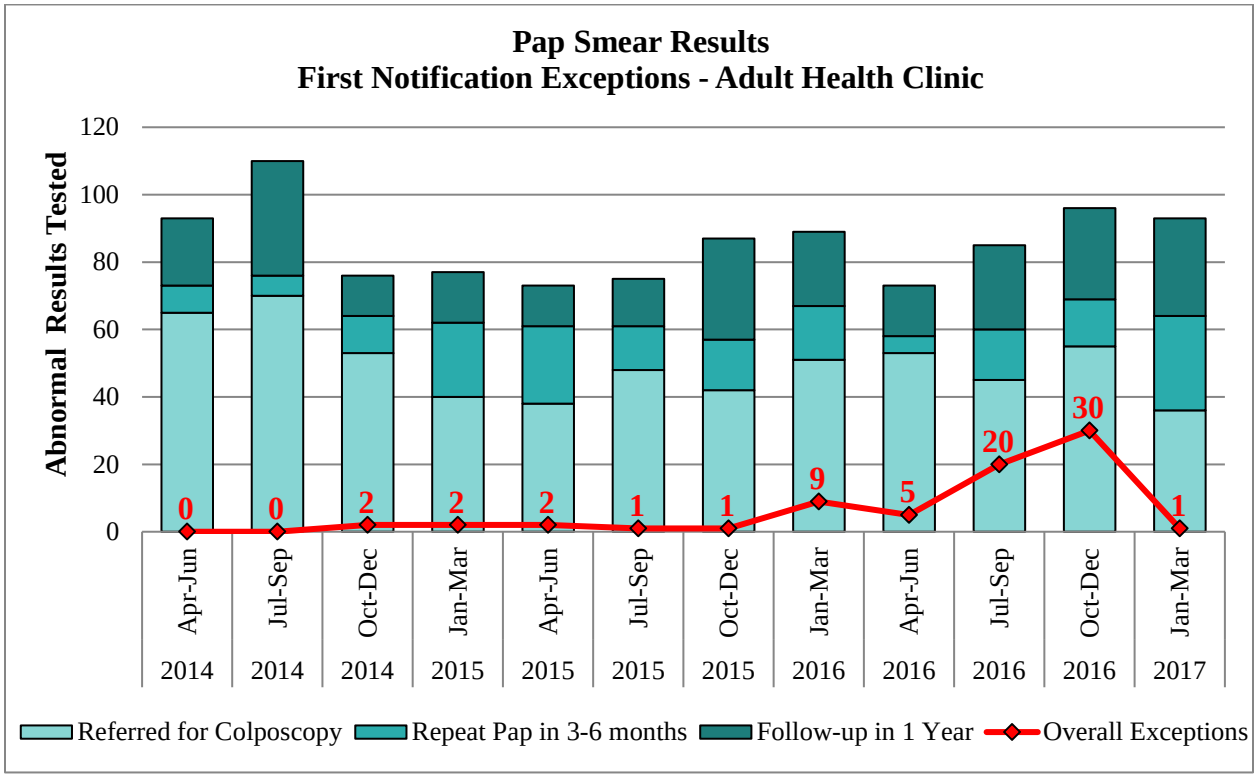
The assessment of the design and operation of key controls indicates Internal Audit's judgment of the process and system design to mitigate risks to an acceptable level.

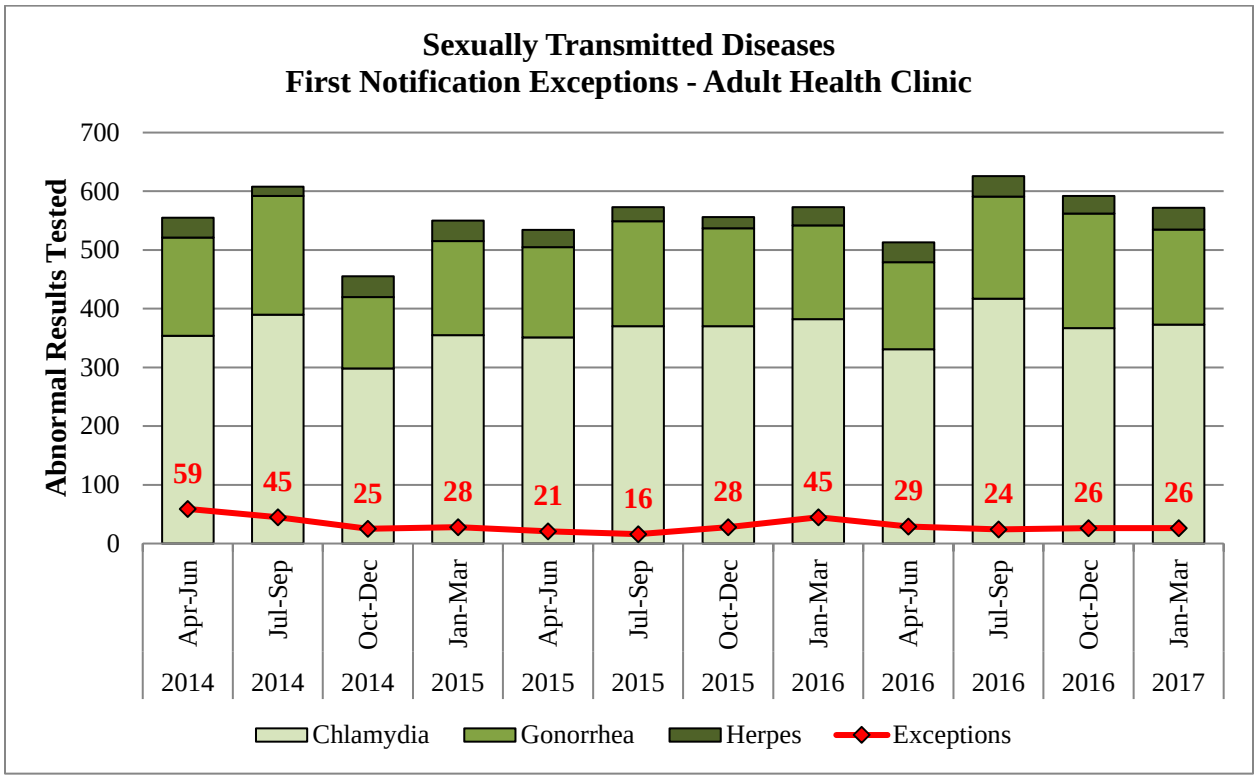
Assessment	Design of Key Controls	Operation of Key Controls
🔴	The process and system design does not appear to be adequate to manage the risk to an acceptable level.	The operation of the process' risk management capabilities is not consistently effective to manage the risk to an acceptable level.
🟡	The process and system design appear to be adequate to manage the risk to an acceptable level. Failure to consistently perform key risk management activities may, however, result in some exposure even if other tasks are completed as designed.	The operation of the process' risk management capabilities is only partially sufficient to manage the risk to an acceptable level.
🟢	The process and system design appear to be adequate to manage the risk to an acceptable level.	The operation of the process' risk management capabilities appears to be sufficient to manage the risk to an acceptable level.

APPENDIX C—Risk Mitigation Strategy Definitions

Risk Mitigation Strategy	Definition
Reduce	Risk response where actions are taken to reduce a risk or its consequences.
Accept	Risk response where no action is taken to affect the risk.
Transfer	Risk response where a portion of the risk is transferred to other parties.
Avoid	Risk response to eliminate the risk by avoiding or withdrawing from the activity giving rise to the risk.

APPENDIX D—Summary of Compliance Exceptions





APPENDIX D—Summary of Compliance Exceptions