# Chapter 23
# Saskatchewan Health Authority—Analyzing Surgical Biopsies in Regina and Saskatoon Labs Efficiently

## 1.0 Main Points

This chapter sets out the results of our audit of the processes that the Saskatchewan Health Authority had to analyze surgical biopsies efficiently at the Regina and Saskatoon labs. A surgical biopsy analysis request from a healthcare provider is considered one patient case, which can comprise multiple specimens. The labs located in Saskatoon and Regina each analyze over 150,000 specimens, or about 45,000 cases, per year. Saskatoon took an average 12.1 days in 2017-18 to provide a surgical biopsy diagnosis report; Regina took an average 18.7 days in 2017-18.

For the 12-month period ended July 15, 2018, the Saskatchewan Health Authority had, other than in the following areas, effective processes to analyze surgical biopsies efficiently in laboratories located in Regina and Saskatoon. The Authority needs to:

- Have a consistent approach for prioritizing surgical biopsy specimens, and have consistent turnaround times for issuing diagnosis reports. Not being consistent across the province could lead to some patients and healthcare providers having to wait longer for their diagnosis than others, and delayed care for patients.

- Assess whether each lab should continue to be accredited under different accreditation bodies. Using different accreditation bodies may result in unnecessary costs and variations in lab operating practices.

- Establish an agreement with the Office of the Chief Coroner regarding the services the labs provide for forensic autopsies. Not having an agreement can create confusion for staff when prioritizing workloads.

- Conduct a cost-benefit analysis of electronically tracking specimens to better understand potential delays in the biopsy analysis process. The labs track a specimen through a manual process, which increases the risk of the labs losing or misidentifying a specimen.

- Educate healthcare providers about how to properly complete a surgical biopsy requisition. Incomplete requisitions can create delays in the lab reporting diagnosis results, and thus delay treatment for the patient.

- Regularly document preventative maintenance completed on surgical biopsy equipment.

Lack of effective processes for performing timely analysis of biopsies affects the Authority's ability to provide timely diagnosis and treatment options. Delayed treatment may result in loss of public confidence in the healthcare system, and reduced quality of life and/or the probability of survival for the patient.

## 2.0 Introduction

A surgical biopsy is a procedure that involves the surgical removal of tissue, often to determine whether a patient has cancer.

Under *The Provincial Health Authority Act*, the Authority is responsible for the planning, organization, delivery, and evaluation of health services in the province. As part of this mandate, the Authority is responsible for providing lab services in the province.

The Authority has eight labs that analyze surgical biopsies for diagnostic purposes (e.g., potential cause of a disease). Three labs are in Saskatoon; two labs are in Regina; and one each in Prince Albert, North Battleford, and Moose Jaw.

- Saskatoon's Labs are located at Royal University Hospital, St. Paul's Hospital, and in the Saskatoon City Hospital
- Regina's Labs are located at the Pasqua Hospital and the Regina General Hospital.

Labs located in Saskatoon and Regina are referral centres for surgical biopsies; in that, they receive biopsies collected from other lab locations (e.g., other labs in and outside the province) for analysis. As a result, the Saskatoon and Regina labs analyze the majority of surgical biopsies done in Saskatchewan. As shown in **Figure 1**, both labs typically analyze over 150,000 specimens per year.[1]

A case is a biopsy analysis request from a healthcare provider. Within a case, there are often multiple specimens. The complexity of a case affects the length of time it takes to complete the analysis of it.

**Figure 1—Number of Specimens Processed by Lab Location from 2015-16 to 2017-18**

| Lab Location [A] | Number of Specimens Preserved for Assessment | | |
|---|---|---|---|
| | 2015-16 | 2016-17 | 2017-18 |
| Saskatoon | 164,750 | 169,827 | 164,687 [B] |
| Regina | 158,263 | 156,613 | 154,619 [C] |
| Prince Albert | 18,618 | 22,187 | 17,655 |
| North Battleford | —[D] | 21,355[D] | 24,066 |
| **Total** | **341,631** | **369,982** | **361,027** |

Source: Saskatchewan Health Authority Records.
[A] Moose Jaw data not available, it did not begin tracking this information until June 2018.
[B] About 46,000 cases.
[C] About 43,000 cases.
[D] North Battleford did not begin tracking this information until May 2016.

## 2.1 Significant Backlogs at the Labs

In May 2018, the Authority reported backlogs in examining biopsies. It noted labs in Regina and Saskatoon had a total of almost 3,000 biopsies awaiting examination. In addition, it indicated Saskatchewan physicians were expressing concern that the long wait times were leading to greater patient anxiety while waiting for diagnosis and treatment options.[2]

[1] Tissue removed through a surgical biopsy procedure is also referred to as a specimen.
[2] Saskatchewan Health Authority Records.

Patients count on lab analysis of biopsies for accurate diagnoses and the consistent quality of their test results.[3]

Research shows that long waits for health care services can contribute to declines in health and can impact the health care system overall.[4] Increased wait times for the results of biopsies and diagnosis cause patients stress and anxiety. In addition, it delays treatment, which can mean the difference between life and death.

Lack of effective processes for performing timely analysis of biopsies affects the ability to provide timely diagnosis and treatment options. Delayed treatment may result in the loss of public confidence in the healthcare system and for some patients, reduced quality of life and/or probability of survival.

## 3.0 Audit Conclusion

**We concluded that for the 12-month period ended July 15, 2018, the Saskatchewan Health Authority had, except for the following areas, effective processes to analyze surgical biopsies efficiently in laboratories located in Regina and Saskatoon. The Authority needs to:**

- **Implement a consistent approach for prioritizing and issuing timely diagnosis reports for surgical biopsies, and identifying inhibiting factors**
- **Evaluate the impact of following different lab accreditation standards and clarify roles and services provided for forensic autopsies with the Office of the Chief Coroner**
- **Conduct a cost-benefit analysis of electronically tracking specimens through the biopsy analysis process**
- **Educate healthcare providers about requesting lab services for surgical biopsies**
- **Regularly document preventative maintenance completed on biopsy equipment**

**Figure 2—Audit Objective, Criteria, and Approach**

**Audit Objective:** Assess the effectiveness of the Saskatchewan Health Authority's processes to analyze surgical biopsies efficiently, for the 12-month period ending July 15, 2018, in the laboratories located in Regina and Saskatoon.

**Audit Criteria:**

Processes to:

1. **Plan for efficient analysis of surgical biopsies**
   - 1.1 Assign responsibility for performing and reporting analysis of surgical biopsies
   - 1.2 Use accepted standards for analyzing surgical biopsies within acceptable timeframes
   - 1.3 Make standards readily accessible
   - 1.4 Track requests for and completion of analysis of biopsies
2. **Analyze surgical biopsies in accordance with standards**
   - 2.1 Prioritize analysis of surgical biopsies
   - 2.2 Maintain adequate biopsy chain of custody
   - 2.3 Utilize qualified medical personnel
   - 2.4 Provide results of biopsy analysis to requisitioning health care professionals

[3] www.cap.org/web/submenu/about?_adf.ctrl-state=ors7hb153_88&_afrLoop=420539191119755#! (20 June 2018)
[4] Health Care in Canada, 2012: *A Focus on Wait Times*, https://secure.cihi.ca/free_products/HCIC2012-FullReport-ENweb.pdf. (28 June 2018).

3. **Monitor the biopsy analysis process**
   - 3.1 Maintain a quality assurance program (e.g., accreditation, quality assurance, equipment maintenance)
   - 3.2 Address factors inhibiting efficient biopsy analysis
   - 3.3 Report key information to senior management

**Audit Approach:**

To conduct this audit, we followed the standards for assurance engagements published in the *CPA Canada Handbook – Assurance* (CSAE 3001). To evaluate the Saskatchewan Health Authority's processes, we used the above criteria based on our related work, reviewed literature including reports of other auditors, and consulted with management. The Authority's management agreed with the above criteria.

We examined the Authority's labs' IT systems and tested 34 surgical biopsy requests through the analysis process. We analyzed policies and procedures that relate to the assessment of surgical biopsies, and interviewed lab staff. We reviewed the maintenance performed on 22 pieces of lab equipment. We consulted with an independent consultant with subject matter expertise in the area. The consultant helped us identify good practice.

This audit did not examine a health care provider's decision to request a biopsy for a patient or a pathologist's interpretation of the biopsy.

# 4.0 Key Findings and Recommendations

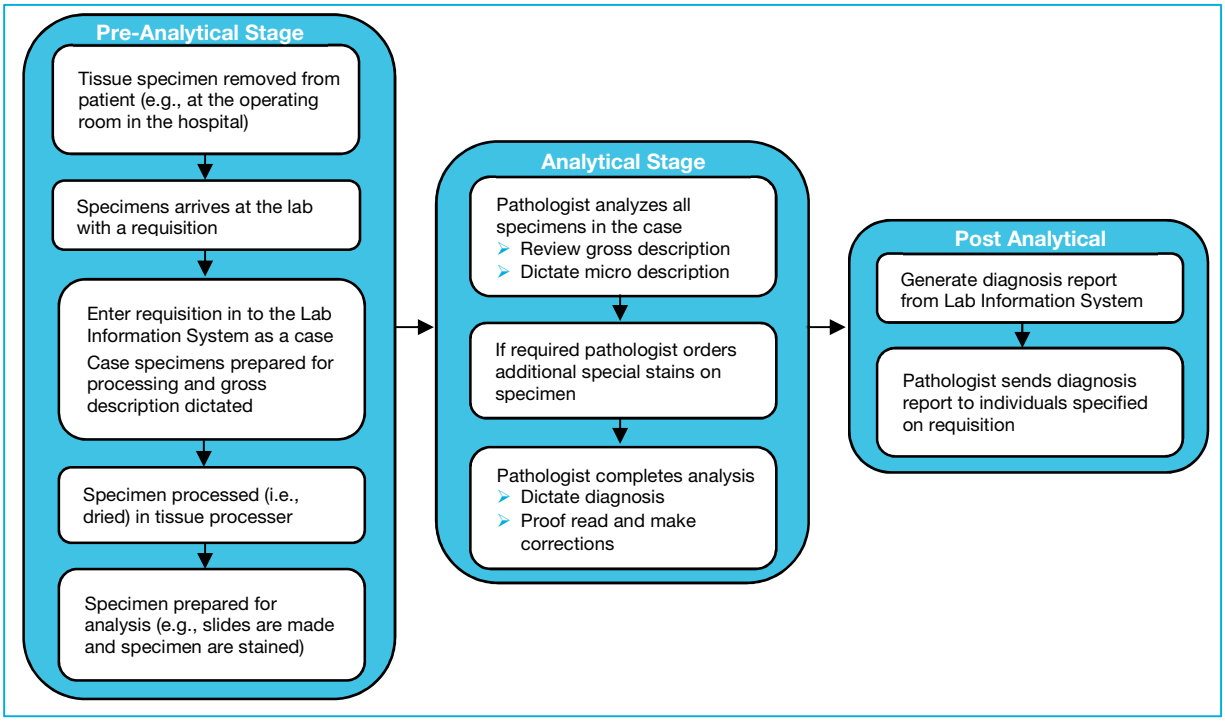
In this report when we refer to the labs, we are referring to Regina and Saskatoon labs.

## 4.1 Surgical Biopsy Process Well-Defined

Each lab maintains well-defined and documented processes to analyze surgical biopsy specimens.

Each lab uses documented policies and standards to clearly set out its processes to receive, analyze, and report on specimens received, and related key stages. **Figure 3** sets out the general process each lab uses.

**Figure 3—Surgical Biopsy Lab Process**




Source: Adapted from 3sHealth process flow diagram.

In general, the processes each lab uses are similar. As shown in **Figure 3**:

- Healthcare providers take a surgical biopsy in a doctor's office or hospital.
- Labs receive requests for analysis and related tissue specimens from requisitioning healthcare providers who make the request using standard forms. Each lab made available to healthcare providers guidance on completing requisition forms. The Regina Lab provided them with a 300-page manual that was electronically searchable. The Saskatoon Lab provides them with a requisition form with notes on how to complete the form appropriately.

We found while the design of forms each lab used varied, information requested was generally consistent. In all cases, templates required healthcare providers requisitioning analysis of a tissue specimen to classify the request into one of three levels (e.g., level 1, 2, or 3 with level 1 being urgent) to indicate how fast it would like the lab to process the specimen.

- Upon receipt, technical lab staff prepares the tissue specimen for analysis (pre-analytical stage). Staff responsible for the pre-analytical stage include medical lab technicians, medical lab assistants, pathology assistants, and histopathology technicians. They are technical staff with varying roles.[5]
- Pathology services are performed by pathologists who are specialized medical doctors who study the causes and effects of diseases.[6] Pathologists complete the analytical and post-analytical stages.
  - Pathologists analyze the specimen (under a microscope) and complete a diagnosis report. Pathologists generate diagnosis reports using each lab's IT system. Both labs use similar IT systems to generate diagnosis reports.
  - Pathologists send completed diagnosis reports to healthcare providers who requisitioned the surgical biopsy analysis, usually through the Province's electronic health records system maintained at eHealth. At the request of healthcare providers, the labs mail paper copies of reports.

All 34 cases we tested followed the lab's standard biopsy processes.

## 4.2 Labs Use Different Accreditation Standards

Each lab uses a different set of industry-recognized accreditation standards to show it has appropriate and suitable standards and processes for analyzing surgical biopsies. At July 2018, the Authority had not determined whether the labs should continue to receive accreditation from different bodies.

Each lab operates under a five-year licence issued by the Ministry of Health in accordance with the *Medical Laboratory Licensing Act* and *The Medical Laboratory Licensing Regulations*. We found the licence of each lab expires in 2020.

[5] Roles of technical staff include:
- Grossing the sample – preparing and cutting a tissue specimen for processing
- Tissue processing – using a piece of equipment to dry out the specimen
- Preparing the slides – cutting the dried tissue and placing it on slides and staining the slides with special chemicals so the pathologist can appropriately diagnose the specimen

[6] Pathology services are primarily concerned with the cause, origin, and nature of disease. They involve the examination of tissues, organs, bodily fluids, and autopsies.

As a condition of the Ministry's licence, each lab (as a licensee) must participate in the Saskatchewan College of Physicians and Surgeons Laboratory Quality Assurance Program. This Program allows labs to choose recognized accreditation bodies to accredit the labs. Accreditation involves both self-assessment and an external peer assessment process.

The former Regina Qu'Appelle Regional Health Authority selected the College of American Pathologists (CAP) to accredit the Regina lab. CAP uses a two-year accreditation cycle. The Regina Lab was last accredited in February 2018 at a cost of about $20,000.

The former Saskatoon Regional Health Authority selected the Western Canada Diagnostic Accreditation Alliance (WCDAA) to accredit the Saskatoon lab. WCDAA uses a four-year accreditation cycle. The Saskatoon Lab was last accredited in September 2018 at a cost of about $25,000.

The Saskatchewan College of Physicians and Surgeons recognizes both CAP and WCDAA as accreditation bodies. CAP is viewed as the optimum standard to follow in lab operations. Our assessment of each set of accreditation review standards found WCDAA includes all the significant standards included in CAP.

Having the labs accredited by different accreditation bodies may result in unnecessary costs and variations in lab operation practices.

1. **We recommend that the Saskatchewan Health Authority assess the impact of the surgical biopsy labs receiving accreditation through different bodies.**

## 4.3 Responsibilities for Surgical Biopsy Process Clearly Assigned other than Relationship with Chief Coroner Office

Except for its relationship with the Office of the Chief Coroner, labs have clearly assigned responsibility to staff for the various analysis stages of biopsies of tissue specimens—pre-analytical, analytical, and post-analytical stages.

Each lab assigns specific staff to key stages in the biopsy process (e.g., preparing and analyzing specimens, creating biopsy reports). See **Figure 4** for staffing levels of each position involved in the biopsy process at the labs.

**Figure 4—Number of Full-time Equivalent Staff by Position as of July 2018 at Each Lab**

| Position | Saskatoon Lab | Regina Lab |
|---|---|---|
| Lab Technologist | 25.3 | 14.5 |
| Lab Assistant | 8.9 | 12.0 |
| Lab Process Worker | 1.6 | --- |
| Pathologist Assistant | 1.0 | 3.0 |
| Histopath Attendant | 0.8 | --- |
| Histopath Assistant | 2.0 | --- |
| Pathologists | 18.9 | 11.0 |
| **Total** | **58.5** | **40.5** |

Source: Saskatchewan Health Authority Records.

We found each lab used a differing approach to set out the responsibilities of its pathologists. Both approaches were reasonable. The Regina Lab maintained up-to-date job descriptions for its pathologists. The Saskatoon Lab used a general employment contract that referred to the professional medical responsibilities of pathologists.

We found each lab used reasonably current job descriptions to state clearly the responsibilities of lab technical staff. The Regina Lab augmented these job descriptions with a detailed up-to date orientation for key technical positions. Both labs give staff a copy of their standards, and keep staff up-to-date on changes to its standards throughout the year.

Lab management kept staff up-to-date on changes in standards through online notifications and group huddles.[7] Each year, each lab required staff to sign-off that they were aware of any changes to the standards.

We found the labs required pathologists and technical staff to be educated, trained, and qualified consistent with the requirements of their job descriptions. Each lab allows staff and pathologists to complete ongoing professional development to stay up-to-date in their roles.

However, both labs did not clearly set out responsibilities of technical staff with respect to handling requests for analysis of forensic autopsies relative to handling other requests for surgical biopsies.

Each lab provides the Office of the Chief Coroner with support including technical lab staff and access to equipment, supplies, and space for the forensic pathologists to conduct forensic autopsies. The Office of the Chief Coroner employs two forensic pathologists, one in the Regina Lab and one in the Saskatoon Lab to complete forensic autopsies.

We found that neither the Authority nor the former regional health authorities had a written agreement with the Office of the Chief Coroner about support provided for forensic autopsies or the responsibilities of each party for the handling of these cases and related specimens.

Not having a written agreement increases the risk of the Authority and the Office not having clear or common expectations and understanding of each party's responsibilities and obligations, and processes to resolve differing views, if any. For example, the Authority and the Office may not have common views on prioritization of surgical biopsies over forensic autopsies. They may also have differing views on the nature and extent of support the Authority provides the Office, and on who pays for that support.

Not having a written agreement with the Office of the Chief Coroner may result in Authority staff within labs making decisions about the handling and processing of requests for biopsy analysis inconsistent with the Authority's expectations. This in turn may cause scheduling conflicts for technical staff, and delays in processing surgical biopsies.

**2. We recommend the Saskatchewan Health Authority enter into a written agreement with the Office of the Chief Coroner about surgical biopsy lab services it provides for forensic autopsies.**

[7] A huddle is a short stand up meeting, usually held at the beginning of a shift.

## 4.4 Consistent Completion Targets and Approaches to Prioritize Requests Needed

The Regina Lab and Saskatoon Lab have differing target turnaround times for processing requests for analysis of surgical biopsies and issuing diagnosis reports. They also use differing approaches to prioritize those requests. In addition, target turnaround times do not always align with good practices.

Each lab receives and processes a large volume of requests for surgical biopsy analysis each year. For example in 2017-18, the Saskatoon Lab processed about 43,000 surgical biopsy cases, and the Regina Lab processed about 46,000 cases. In 2017-18, they processed 228 biopsies related to forensic autopsies.

Good practices have varied target turnaround times for processing and issuing diagnosis reports based on an assessment of both the priority and complexity of the biopsy. Good practice allows additional time to prepare and assess the specimen due to the complex nature of assessment.[8] For example, good practice suggests the following categories and turnaround-time targets for issuing diagnosis reports:

- Urgent Biopsies – 24 hours. Generally, if the lab needs to do an analysis on a biopsy received from the operating room immediately, this is an urgent biopsy.
- Small Biopsies – 3 business days. Generally, small biopsies are tissue specimen from a prostate or lung that is smaller, and the lab can process the specimen upon receipt.
- Routine Biopsies – 5 business days. Generally, routine biopsies are tissue specimen that may be benign.
- Breast Cancer Biopsies – 6 to 15 business days.[9]

Consistent with good practices, the Saskatoon Lab varied target turnaround times for processing and issuing diagnosis reports based on an assessment of both priority and the complexity of the biopsy. It communicated its process to classify requests to staff in a written policy. This policy helps staff determine which requests to process first.

As outlined in **Figure 5**, the Saskatoon Lab's policy requires staff to classify requests using a number of criteria, including the type of biopsy specimen. It appropriately gives lab staff authority to reclassify a specimen when a healthcare provider labels a requisition as urgent (e.g., Priority 1), and they determine specimen does not meet the criteria of a Priority 1 specimen.

**Figure 5—Saskatoon Lab Prioritization Policy and Targeted Timeframes**

| Assessed Priority Level | Examples of Prioritized Surgical Biopsy Specimens | Targeted Turnaround Times |
|---|---|---|
| Priority 1 | ➢ Bone marrow<br>➢ Kidney<br>➢ Transplant Biopsies | Processing: Less than 48 hours<br>Diagnosis Report: 24 – 72 hours |

[8] After the first sections of tissues are seen under the microscope, the pathologist may want to look at more sections of the tissue or ask for special stains to make an accurate diagnosis. In these cases, extra pieces of the tissue might need processing and staining.
[9] Sunnybrook Health Sciences Centre, https://uoftorthopaedics.ca/hospitals/sunnybrook-health-sciences-centre, (02 October 2018).

| Assessed Priority Level | Examples of Prioritized Surgical Biopsy Specimens | Targeted Turnaround Times |
|---|---|---|
| Priority 2 | ➢ Lung<br>➢ Prostate<br>➢ Breast<br>➢ Liver<br>➢ Biopsy labelled | Processing: Less than 48 hours<br>Diagnosis Report: 3 to 8 calendar days |
| Priority 3 | ➢ All other specimens | Processing: 48 to 72 hours<br>Diagnosis Report: 14 calendar days |

Source: Saskatchewan Health Authority Records.

Consistent with good practices, the Regina Lab varied, to some extent, target turnaround times for processing and issuing diagnosis reports based on an assessment of both priority and the complexity of the biopsy. For example, it had a turnaround target for providing diagnosis reports within five business days of receipt of the request. In addition, lab staff indicated they informally treat specimens classified as urgent, or received from operating rooms and breast tissue samples as higher priority. They aim to process higher priority specimens within 24 hours of receipt.

Other than its documented five-day turnaround time target for biopsy specimens, the Regina Lab did not have documented prioritization classifications and associated target turnaround times. Lack of documented guidelines increases the risk that staff do not prioritize requests consistently.

Like the Saskatoon Lab, the Regina Lab gives staff authority to reclassify a specimen from that of the requisitioning healthcare provider at the time of receipt of the requisition. Neither lab requires staff to document their classification when it differs from the requisitioning healthcare provider.

In addition, we found that neither lab had written guidance about classifying the priority of processing forensic autopsies. Staff at labs indicated that they prioritize forensic autopsies over surgical biopsies, and complete the autopsies before returning to their regular duties.

We also found that the target turnaround times of each lab were not always consistent with good practice. We found:

- The Saskatoon Lab allowed more time than good practice for some of its turnaround-time targets, and less time for its turnaround-time targets for others. For example, its turnaround time for issuing diagnosis reports for Priority 3 biopsy specimens is 14 days compared to good practices' suggestion of 5 days for routine biopsies. In another example, its turnaround time for issuing diagnosis reports for breast cancer biopsies is faster than good practice.

- The Regina Lab's documented target turnaround time of five business days was consistent with good practice for routine biopsies. As previously noted, it did not have written target turnaround times for other types of requests.

Inconsistent prioritization strategy for processing and analyzing specimens may result in some patients and healthcare providers having to wait longer for diagnosis results than others, resulting in delayed care for patients. Inconsistent target turnaround times for processing and providing diagnosis results leads to providing patient care inconsistently across the province.

3. **We recommend the Saskatchewan Health Authority implement a consistent approach for prioritizing and issuing timely diagnosis reports for surgical biopsies.**

## 4.5 Better Tracking of Specimens Needed

Neither lab maintains information about surgical biopsy specimens in a manner that enables ready tracking of the location of a specimen throughout the entire analysis process. In addition, neither lab maintains information regarding the complexity of a case and the time taken to complete each key point of analysis.

As shown in **Figure 6**, each lab tracks some information in the biopsy analysis process electronically, and all the information manually. Good practice expects that the labs would track this information electronically to easily identify where a specimen is at in the biopsy analysis process.

**Figure 6—Key Tracking Points of the Biopsy Analysis Process by Lab**

| Key Tracking Point by Stage | Saskatoon Lab Tracks | | Regina Lab Tracks | |
|---|---|---|---|---|
| | Electronically | Manually | Electronically | Manually |
| Pre-Analytical Stage | | | | |
| Classify priority of Request for Analysis | No | Yes [A] | No | Yes [A] |
| Date and time specimen is received by the lab | Yes | Yes | No [B] | Yes |
| Date and time the specimen is prepared for the tissue processor | No | Yes | Yes | Yes |
| Date and time the specimen is processed in the tissue processor | No | Yes | No | Yes |
| Date and time the specimen is prepared for analysis, includes applying the specimen to a slide and applying stains to the slide so the pathologist can diagnose the specimen | No | Yes | No | Yes |
| Analytical Stage | | | | |
| Date and time the slides are delivered to the pathologist | No | Yes | No | Yes |
| Post Analytical Stage | | | | |
| Date and time the pathologist sends the diagnosis report to the requisitioning health care provider | Yes | Yes | Yes | Yes |

Source: Key tracking points based on good practice; what is tracked electronically and manually at the labs based on Saskatchewan Health Authority records.
[A] Labs do not document when they change the priority of the Request for Analysis from the healthcare professional's classification.
[B] Regina enters its data entry date and time, which is not necessarily the same date and time as its receipt of the specimen.

In addition, the labs do not keep consistent electronic information. For example, as also shown in **Figure 6**, only Regina records electronically the date and time a specimen is prepared. Also, Regina records the date and time of entry of request instead of the actual date and time of its receipt of a specimen.

Furthermore, neither lab keeps track of when it reclassifies the priority of requests from that of the requisitioning healthcare provider.

Management at both labs indicated that their current IT system does not have the capability to track information on all key tracking points. At July 2018, the Saskatoon Lab had plans to implement a lab tracking IT system in December 2018. It bought this system

in April 2018 using a City Hospital Foundation donation.[10] At July 2018, the Regina Lab did not have a plan to purchase a similar tracking system.

Once implemented, Saskatoon's new lab tracking system will assign a barcode to each biopsy specimen received. The Saskatoon Lab expects its staff will scan the barcode at each step in the process. This will update the system to identify when staff began and completed each key tracking point.

Management at both labs indicated they have misidentified and misplaced specimens, which has delayed the analysis process. In addition, both labs know they, on average, take longer to process specimens than their target turnaround times. However, neither know the key points that are delaying the analysis process (see **Recommendation 5**). Not having an adequate tracking system makes it labour intensive for the labs to determine if their target turnaround times are reasonable, and to determine reasons not achieving them.

As previously noted, each lab receives and processes over 40,000 cases each year. Many different lab staff are involved in the handling and processing of the surgical biopsy specimens.

Collecting and maintaining information manually results in labs not being able to easily identify who has control of the specimen, or determine how long each part (point) of the process takes (e.g., how long it takes lab technical staff to prepare the specimen for analysis). This can result in staff wasting time locating a specimen.

Not having an adequate tracking system increases the risk of labs losing or misidentifying specimens in the process which may result in labs providing untimely or inaccurate diagnosis results to health care providers, and in turn, their patients.

4. **We recommend the Saskatchewan Health Authority assess the cost-benefit of electronically tracking the location of surgical biopsy specimens throughout the key stages of the lab analysis process.**

## 4.6 Assessment of Inhibiting Factors in Providing Timely Diagnosis Required

The Saskatchewan Health Authority does not know why labs are not achieving turnaround targets, or whether its labs are appropriately staffed.

Neither lab tracks the number of surgical biopsy analysis requests by their complexity and priority (e.g., classification by level 1, 2, or 3), or the time it takes to complete each key tracking point in the biopsy analysis process. In addition, neither lab tracks workload of technical staff to evaluate the productivity of the work units.

Both labs report to the Executive Director of Pathology and Laboratory Services monthly on the number of specimen received and prepared for analysis as compared to their target turnaround times. While the 2017-18 monthly reports showed each lab did not meet their target turnaround times, they did not provide insight into or reasons for not doing so.

[10] The Saskatoon Lab received a donation through the City Hospital Foundation on January 21, 2016, to purchase a lab tracking IT system.

Using the results of our testing of 34 surgical biopsy requests, and assessment of data compiled from each lab's IT system, we also found neither lab is issuing patient results timely. We found:

- The number of days it took the labs to issue diagnosis reports for the 34 requests we tested ranged from 1 to 222 days, resulting in an average of 35.4 days.
- For the 34 requests we tested, we found biopsies marked as urgent (Priority 1) took 1 to 222 days to complete the assessment; biopsies marked as semi-urgent (Priority 2) took 5 to 17 days to complete, and biopsies marked as routine (Priority 3) took 1 to 127 days to complete.
- The Regina Lab issued diagnosis reports, on average, later than its target turnaround time of 5 days. Its average for issuing diagnosis reports in the 2017-18 fiscal year was 18.7 days.
- The Saskatoon Lab issued diagnosis reports, on average, for the 2017-18 fiscal year, within 12.1 days. In one instance, it took the Saskatoon lab 222 days to issue a diagnosis report. Due to the limitations of its lab IT system, the Saskatoon Lab does not keep track of processing and issuance results based on its prioritization levels.

Lab management indicated they are not achieving target turnaround times because they do not have enough technical staff and pathologists. We found in 2015 they shared this view with senior management of their former health authorities (Regina Qu'Appelle and Saskatoon) through a joint report on trends in surgical pathology and status of this practice in Canada and Saskatchewan.[11]

The 2015 joint report indicated surgical pathology practices were under new pressures because of advances in biology and treatment along with increased public expectations of accurate diagnosis reports. It noted labs in Saskatchewan had significant risks of diagnostic error because of, in part, staff shortages, structural issues, and lack of a co-ordinated approach. The report called for the labs to integrate the surgical pathology practice in the province to better utilize the skills each individual pathologist has, and better identify what specialties the province lacks.

Since the 2015 joint review, both labs took some steps to overcome challenges identified in the report. For example:

- The Saskatoon Lab changed its workflow based on a September 2014 review. It added additional shifts for lab technical staff, rotated assigned tasks more frequently, and created new work areas to maximize efficiencies. These changes reduced its average time to process a surgical biopsy from 24.3 days in 2016-17 to 12.1 days in 2017-18.
- In July 2018, the Regina Lab reviewed its workflow and identified changes required. As of July 2018, it was in the early planning stages of renovating the Lab to make its biopsy process more efficient. In addition, it was starting to analyze its technical staffing needs.
- In July 2018, pathologists began assisting in the preparation process in both Regina and Saskatoon to reduce the backlog of biopsy analysis cases.

[11] Surgical pathology is the study of tissues removed from living patients during surgery to help diagnose a disease and determine a treatment plan.

However, as of July 2018, neither the former health authorities nor the Saskatchewan Health Authority had further analyzed the potential for a province-wide integrated surgical pathology practice. In addition, neither lab had formally determined whether its target turnaround times were realistic, or analyzed reasons for delays.

By not meeting their turnaround-time targets, the labs are putting patients' health at risk, as timely diagnosis is required to begin any required treatment.

5. **We recommend the Saskatchewan Health Authority formally assess the surgical biopsy process at its surgical biopsy labs to identify factors inhibiting timely diagnosis.**

## 4.7 Incomplete Requisitions Received from Healthcare Providers

Requisitions that each lab receives from healthcare providers are not always complete and/or the priority of the request is not always properly classified (e.g., priority 1 [urgent] to 3 [routine]).

Our testing of 34 requests found one instance where a requisition form was missing key information. This error on the requisition resulted in a delay of 44 business days in completing the diagnosis report for the patient.

The results of our testing is similar to the Regina Lab's findings. The Regina Lab reported that up to 2.6% of requisitions received in each quarter of 2017-18 were incomplete. In 2017-18, the Regina Lab received 1,700 requisitions from health care providers that were incomplete. The Saskatoon Lab did not track or report on incomplete requisitions.

In addition, the Regina Lab is aware some requisitioning healthcare providers classify their requests as urgent more frequently than in prior years. While it has not tracked how many requests classified as urgent did not qualify as urgent, it thinks healthcare providers do so because of its backlog of outstanding cases.

Incomplete requisition forms from health care providers can result in delays to diagnosing a patient's biopsy. Providing health care providers with training or better guidance on completing requisitions, and when to identify a biopsy as urgent could help reduce the number of errors on requisitions received.

6. **We recommend the Saskatchewan Health Authority educate healthcare providers on properly completing surgical biopsy requisitions for Regina and Saskatoon labs.**

## 4.8 Quality Assurance Reporting Generally Consistent with Good Practice

Each lab provides senior management with quality assurance information that is generally consistent with good practice.

Under each lab's accreditation requirements, each lab must have a quality assurance program. This includes a review of errors, complaints or incidents, and a system for monitoring the biopsy process (e.g., number of outstanding cases). For example, in

2017-18, reports at the labs indicated that there were three specimens not labelled or incorrectly labelled and two instances of a missing specimen.

Each lab gives senior management regular reports on its quality assurance activities. In addition, lab management meet on a regular basis to discuss quality assurance. The Saskatoon Lab reports twice a year, and the Regina Lab reports each quarter.

We found the content of each report was generally consistent, with each lab using a standard format for each reporting period. For example, both labs report the number of outstanding cases daily, that is, the number of requests for which it has not issued a diagnosis report. For example, as of September 25, 2018, the Saskatoon Lab had 503 cases outstanding, and the Regina Lab had 848 cases outstanding.[12] The Saskatoon Lab reports trends on the number of specimens and cases received throughout the year. The Regina Lab does not.

## 4.9 Equipment Preventative Maintenance Not Always Documented

The Authority does not require the labs to track the completion of preventative maintenance. The Saskatoon Lab does not regularly keep track of when technical staff do preventative maintenance on lab equipment involved in the surgical biopsy analysis process.

Each lab has over 50 pieces of surgical biopsy equipment (e.g., tissue processors, slide printers, and slide stainers).

Each lab uses technical lab staff (with suitable expertise) to maintain relatively simple equipment (e.g., machine that embeds the tissue in wax) and manufacturers of lab equipment to do preventative maintenance (e.g., calibration) on complex or sensitive lab equipment (e.g., tissue processors).

Each lab had sufficient service agreements in place with related equipment manufacturers that set out the expected nature and extent of maintenance. Each lab maintains the service records to keep track of maintenance manufacturers complete.

For all ten pieces of equipment we reviewed at the Regina Lab, the Regina Lab kept adequate records of maintenance completed including records of who did the maintenance, and when. Its technical staff had maintained two of the ten pieces we examined; the other pieces received regular maintenance from service providers.

However, the Saskatoon Lab did not always keep track of preventative maintenance completed by technical staff. For all six pieces of lab equipment we tested, that the Saskatoon Lab staff was responsible for maintaining, the lab did not keep track of when its staff last performed preventative maintenance. Management indicated the equipment received maintenance within the last 12 months. Its technical staff had maintained 6 of the 12 pieces we examined. The other six pieces of equipment had received regular maintenance from service providers.

Not documenting when preventative maintenance on surgical biopsy equipment is completed, and by whom increases the risk of not completing maintenance as expected. In addition, without documentation, management cannot be sure maintenance is

[12] Saskatchewan Health Authority Records.

occurring as expected. Lab equipment must receive appropriate maintenance to ensure analysis is properly completed.

7. **We recommend the Saskatchewan Health Authority require its labs to keep records of preventative maintenance completed by technical staff on its surgical biopsy equipment.**

## 5.0 Selected References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