

Guidelines on the Collection and Shipment of Specimens Submitted for STI Testing

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Introduction

- KHEL Virology/Serology Unit operates under Clinical Laboratory Improvement Amendments (CLIA) regulatory guidelines to ensure accurate testing and reporting.
- CLIA guidelines require high quality specimens with a complete submission form matching the submitted specimens' unique patient identifiers, otherwise specimens will be rejected.

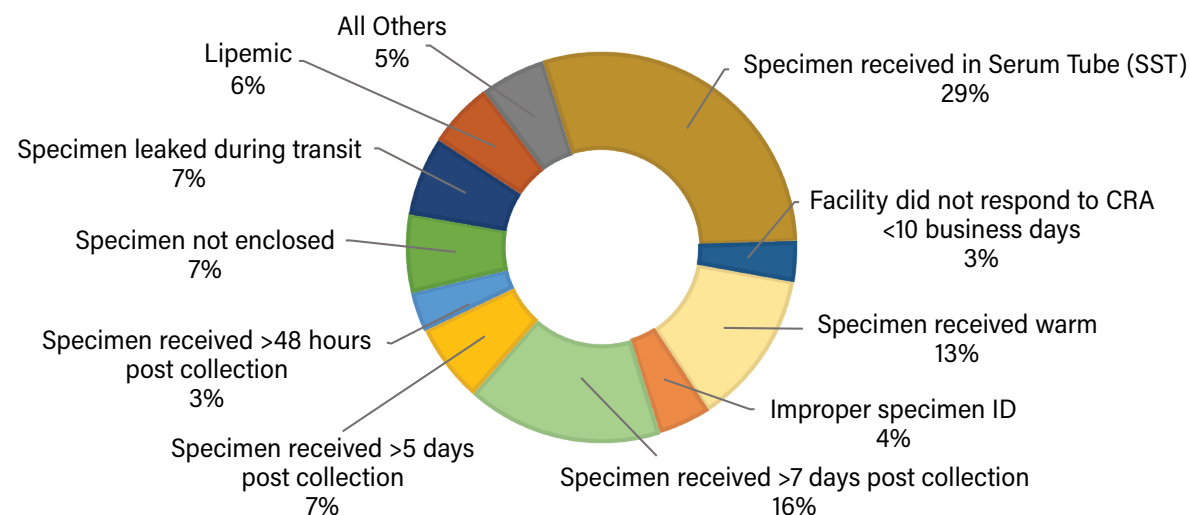
Objectives

- Educate KHEL's cooperators as to the preventable causes of specimen rejection.
- Educate KHEL's cooperators as to the preventable causes of delayed testing and reporting.
- Provide KHEL's cooperators with resources to mitigate specimen rejection, delayed testing, and delayed reporting.

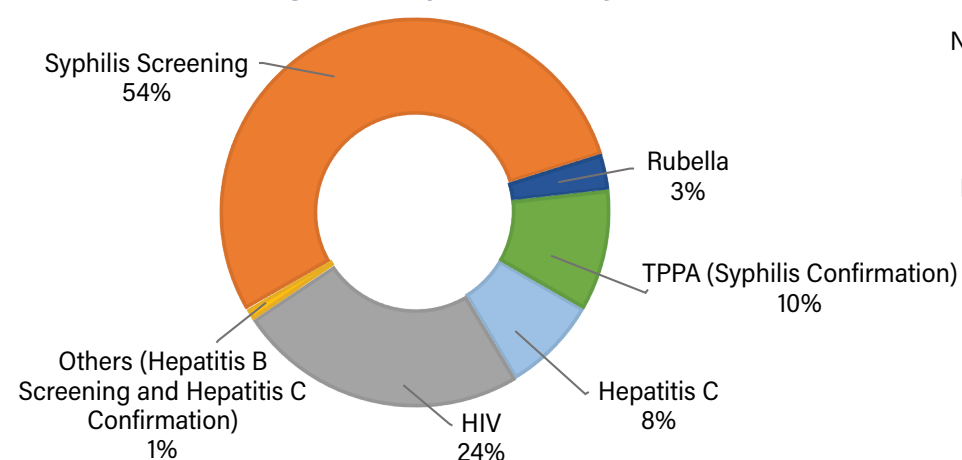
Methods

The rejected specimen (N=1,277) and facility outreach database (N=2,425) content from January 1, 2020 through June 30, 2023 was analyzed to identify the most common reasons for specimen rejection, testing delay, or delay in reporting of results to a submitting facility.

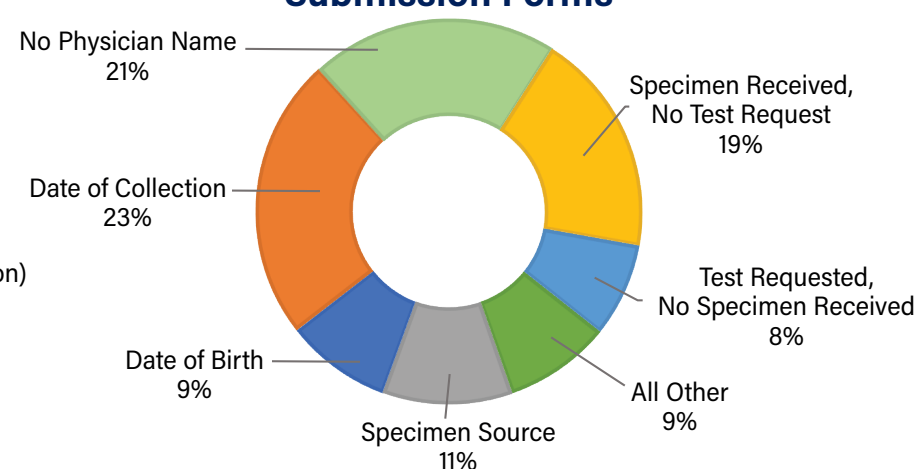
Common Causes for Specimen Rejection



Percentage of Rejections by Test



Information Commonly Missing from Submission Forms



Results

- The primary reasons for specimen rejection involve incorrect collection, handling, and transport of specimens prior to their arrival in the Virology/ Serology unit.
- The primary cause of specimen rejection, 29%, is the specimen arrived in a specimen separation tube, rather than poured into a specimen tube.
- The screening and confirmation assays most impacted by specimen rejection are those for syphilis testing, 64%.
- The primary cause of facility outreach is a missing date of collection, 23%, on the specimen submission form.

Discussion

- The infections with the most rejected specimens can be deadly if not treated appropriately. Delays in access to medication, behavioral counseling, and public assistance speeds the spread of the infection within a community.
- Syphilis assays require the most rigorous specimen quality standards. These specimens must arrive cold, in specimen tubes, and within five days of collection.
- KHEL provides the necessary specimen tubes, free of charge to any submitting facility.

Conclusions

- Each rejected specimen is a missed opportunity to provide quality medical care to a patient and their community.
- Collection and submission instructions are on the back of each submission form, as well as the [KHEL website](#).
- If any submitting facility has any questions, please call or email the KHEL contact information provided on the submission form and on the KHEL website, linked above.
- Bibliography available on request.

Acknowledgements

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