Targeting Rejection: Analysis of Specimen Acceptability and Rejection, and Framework for Identifying Interventions in a Single Tertiary Healthcare Facility

Lisa Rooper,¹ Jamal Carter,¹ John Hargrove,² Sheri Hoffmann,² and Stefan Riedel^{1,2*}

¹Department of Pathology, School of Medicine, The Johns Hopkins University, Baltimore, Maryland

²Department of Pathology, Johns Hopkins Bayview Medical Center, Baltimore, Maryland

Objectives: Assessment of specimen rejection rates is an important laboratory quality measure for laboratories because of a potential negative impact on patient care. Here, we examined reasons for specimen rejection at a single, tertiary care healthcare institution and propose a framework for designing an efficient intervention. **Methods:** During a 1-year period, we identified all specimens rejected at our hospital and performed an analysis of a wide range of associated variables: reason for rejection, patient location, type of phlebotomist, tests ordered, priority status, collection container used, transport time. **Results:** Clotted and hemolyzed specimens accounted for the majority of

rejected specimens, but significant differences in reasons for specimen rejection existed between patient care areas. Eighty-five percent of rejected specimens came from the Emergency Department and eight other inpatient care areas. Registered nurses drew approximately 85% of rejected specimens, while laboratory phlebotomy staff drew only 4%. **Conclusions:** While hemolysis and clotting are primary causes for specimen rejection, collection of all available data regarding specimen rejection data is essential for laboratories determining which factors are most significant causes of specimen rejection. J. Clin. Lab. Anal. 31:e22060, 2017. © 2016 Wiley Periodicals, Inc.

Key words: laboratory management; laboratory quality assurance; specimen rejection rate

INTRODUCTION

The rejection of phlebotomy specimens may be considered a clinical laboratory problem, but it has a wide range of direct negative implications for patient care. On the most obvious level, rejected specimens lead to the inconvenience and discomfort of repeated specimen collection, with accompanying delay in reporting test results. Specimen rejection leads to a median lag of 65 min in availability of test results (1), potentially postponing the availability of critical values, the ability to make diagnoses, and the initiation or cessation of treatment. But specimen rejection can also lead to the abandonment of tests, with as many as 48.3% of canceled tests never being redrawn and reported (2) and results never being known. Although rejection might rarely cause an unnecessary test to be reconsidered, it more often leads to additional intervention and expense. One model suggested that the consequences of rejected specimens cost \$357.15 for each hospital

inpatient and \$337.05 for each hospital outpatient per year, altogether comprising between 0.23% and 1.2% of total hospital operating costs (3). Because of these many negative consequences of specimen rejection, monitoring of specimen acceptability is an important quality assurance measure within the clinical laboratory. Many studies have evaluated this issue in individual laboratories and have reported rejection rates ranging from 0.1% to 3.49% (4–6). While there is no formal requirement for specimen acceptability, the College of American Pathologists (CAP) recommends that each institution compare its internal rates of specimen rejection to benchmarks from multi-institutional

*Correspondence to: Stefan Riedel, Beth Israel Deaconess Medical Center, Department of Pathology, Harvard Medical School, 330 Brookline Avenue, Ya-309, Boston, MA 02215. E-mail: sriedel@bidmc.harvard.edu

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studies (GEN.20316), with a low threshold for action if rejection rates climb too high. The most recent such Q-probes studies reported a median rejection rate of 0.31% (7), while a subsequent Q-tracks study highlighted 0.28% as a target for best performers (8). Based on data from these studies, our institution regards 0.5% rejection as the maximum acceptable threshold for specimen rejection. Unfortunately, little guidance is available for laboratories that find themselves with an excessive proportion of rejected specimens. Most studies that evaluated this issue in individual laboratories simply cataloged the reasons for rejection, including specimen hemolysis, clotting, mislabeled specimens, and insufficient quantity for test (2, 6, 9–18). Additionally, a separate body of literature has reported phlebotomy interventions to ameliorate specific acceptability issues, such as techniques to mitigate hemolysis (19–21) and incorrect labeling (22, 23). But there is no widely available framework for helping any given laboratory identify why its own specimens are rejected and target which interventions would be most appropriate. The most detailed advice available is summarized at the end of the aforementioned Q-probes study, which simply recommends identifying and monitoring significant variables, and suggests container size, container type, specimen type, and collection personnel as initial considerations (7). At our hospital laboratories, we routinely monitor overall specimen rejection rates, as recommended by CAP. A month-to-month fluctuation of specimen rejection rates was noticed with rates being recurrently above our 0.5% intervention threshold for certain patient care locations within the hospital (e.g., emergency department). An initial, “superficial” analysis of specimen rejection data, however, did not allow us to identify an obvious root cause of this problem. As such, we initiated a comprehensive analysis of the variables affecting specimen acceptability in our laboratory. This analysis was designed to identify the most significant reasons for specimen rejection and allow the development of efficient and cost-effective interventions. In this article, we describe the format and findings of this single-laboratory analysis and propose an algorithm that could potentially benefit other institutions to identify their most important causes of specimen rejection.

MATERIALS AND METHODS

This study was conducted at our tertiary care, 477 bed academic medical center (Johns Hopkins Bayview Medical Center, JHBMC) that serves as both a primary hospital for the surrounding urban community as well as a specialist center within our academic, tertiary care hospital network; specialty centers and/or

departments include rheumatology, allergy and immunology, pulmonology, and an ICU for patients with burn wounds, serving as a regional burn center for adult patients. The Clinical Pathology laboratories provide STAT and routine laboratory testing for a complex patient population that includes a busy emergency department, adult medical, cardiac, surgical, and neurosurgical intensive care units (ICU), a neonatal intensive care unit, a burn ICU/center, labor and delivery, additional adult inpatient, pediatric inpatient, and subacute rehabilitation wards, and a wide range of outpatient clinics. Laboratory testing is performed at either the central laboratory located within the Pathology Department at JHBMC, or at reference laboratories both within and outside our healthcare network. However, all patient specimens collected at all JHBMC clinical sites are initially received at our central laboratory processing area for either in-house testing or referral to one of the reference laboratories.

This study was performed as part of an internal quality improvement initiative at the JHBMC and was approved by the Johns Hopkins Medical Institutions Institutional Review Board (IRB). We conducted a retrospective search of the JHBMC laboratory information system (LIS), to identify all phlebotomy specimens that were received in our laboratory between July 30, 2013 and July 30, 2014. These specimens included samples for arterial blood gas analysis, various chemistry, hematology, and coagulation tests, but did not include specimens for testing in microbiology or point of care specimens. The total number of specimens collected as well as those that were rejected during this time period was tabulated according to date and hospital location. The following attributes were collected for all rejected specimens when available: tests ordered, test priority, patient location, phlebotomist alias, type of tube, time of draw, time of receipt, interval from draw to receipt, and reason for rejection. All available phlebotomist aliases were queried in the JHBMC employee directory, and corresponding job titles were tabulated. The number of rejected specimens per individual patient was also noted.

All specimens included in this study were processed according to routine laboratory procedures at the time they were received at the JHBMC laboratory. Phlebotomy specimens were accessioned in the central specimen receiving area within the core laboratory, where they were initially assessed for acceptability based on our standard operating procedures. In general, most tests required a minimum volume of 1 ml and had to be received in appropriate sample collection tubes. While arterial blood gas specimens were accepted in both, blood gas syringes or capillary tubes,

all other specimens had to be drawn in standard-size phlebotomy tubes. After processing, specimens were directed to the critical care, chemistry, hematology, and coagulation laboratory sections, or sent out to reference laboratories, at which point additional assessments of acceptability were made if necessary. For all specimens rejected at any point during this process, laboratory personnel informed clinical staff of the rejection and instructed them to reorder and redraw the sample for testing.

For the purposes of this study, all administrative units that shared a similar clinical function, patient population, and clinical staff were grouped together (e.g., various routine general medicine care units; conventional and fast track emergency divisions). Personnel performing phlebotomy procedures, who did not carry the title of registered nurse, licensed nurse practitioner, patient care technician, or laboratory phlebotomist, were also combined into a single group for our data analyses. Finally, an initial evaluation of efficacy of the educational intervention, described in this analysis was performed by comparing overall specimen rejection rates for the time period between July 2013 and July 2014 and the time period between July 2014 and July 2015. Data assessment and statistical analyses were performed using Microsoft Excel (Microsoft Corporation, Redmond, WA) and the R statistical package (www.r-project.org). Categorical data were compared using the chi-square test of independence.

RESULTS

A total of 460 003 phlebotomy specimens were submitted to the JHBMC laboratory between July 30, 2013 and July 30, 2014. Of these, 3425 (0.74%) were rejected. Reasons for rejection included hemolysis, clotting, insufficient quantity for test, time delay, incorrect temperature, loss of specimens during transport, and incorrect labeling (Table 1). Overall, clotting was the most common cause of specimen rejection, comprising 1802 (52.8%) rejected specimens, and hemolysis was the second most common cause, with 1426 (41.8%) rejections. Because these two categories collectively comprised the vast majority (94.6%) of specimens rejected at JHBMC, they were targeted for further investigation.

Rejected specimens were seen from virtually all clinical locations at JHBMC, including 23 inpatient units, 21 outpatient clinics, and 2 emergency locations. The single most common location for having specimens rejected from being processed and analyzed was the emergency department (ED), which accounted for 842 (26.96%) of all rejected specimens. Considering rates of specimen rejection by unit, the NICU had the

TABLE 1. Overall Proportions and Reasons for Specimen Rejection

Reason for rejection	Rejected specimens (N)(Total 3425)	Percentage (%) rejected specimens
Clotted	1802	52.83
Hemolyzed	1426	41.81
Insufficient quantity	170	4.98
Mislabeled	11	0.32
Time delay	10	0.29
Other problems*	6	0.18

*Other problems include specimen transport at incorrect temperature, incorrect specimen collection method/container, and loss of specimens during transport.

highest rate of specimen rejection overall, with 1.92% of all specimens drawn at that location being rejected. The ED and trauma locations also had higher rates of specimen rejection (1.08%, each) when compared to other locations within our hospital. Including these three units, 10 locations submitting/drawing blood specimens were responsible for 84.12% of all rejected specimens at JHBMC (Table 2). All other inpatient locations accounted for 13.03% of all rejected specimens and all other outpatient locations had only 2.85% of specimen rejections. As such, these 10 locations with high rates of specimen rejection were considered for further, more detailed analysis.

There was a significant difference in the reasons for specimen rejection seen in these 10 units with the highest rejection volumes (Fig. 1). Although the ED had high numbers of both clotted and hemolyzed specimens, the rate of rejection because of hemolysis for ED specimens was relatively higher than that rate for specimens collected at other locations ($P < 0.001$).

TABLE 2. Proportions of Rejected Specimens by Site of Service

Site of specimen collection	Rejected specimens (N) (Total 2627)	Percentage (%) rejected specimens (84.12%)	% of specimens collected at site
Emergency Department	842	26.96	1.08
Neonatal ICU	513	16.43	1.92
Medical ICU	267	8.55	0.61
Cardiac ICU	218	6.98	0.62
Medical floor	209	6.69	0.21
Telemetry unit	145	4.64	0.31
Neurological CCU	138	4.42	0.44
Surgical ICU	123	3.94	0.60
Surgery floor	90	2.88	0.19
ED-Trauma	82	2.63	1.08

ICU, Intensive Care Unit; ED, Emergency Department.

Fig. 1. Proportions of specimens rejected for clotting and hemolysis by patient care location. Patient care locations included Emergency Department (ED), ED trauma bay (TRA), Cardiac Intensive Care Unit (CICU), General Medicine Ward (MED), Medical Intensive Care Unit (MICU), Neurological Critical Care Unit (NCCU), Neonatal Intensive Care Unit (NICU), Telemetry Unit (TELE), Surgical Intensive Care Unit (SICU), and General Surgical Ward (SURG).

The medical intensive care unit (MICU), cardiac intensive care unit (CICU), and telemetry unit (TELE) had a similar predominance of hemolysis ($P < 0.001$ for each of these sites). In contrast, the neonatal intensive care unit (NICU) had a higher proportion of clotted specimens when compared to other locations ($P < 0.001$). The overall rate of specimen rejection also varied widely across these 10 units. Although the total numbers of rejected specimens were relatively equivalent among most units, the MICU, CICU, and surgical intensive care units (SICU) all had higher rejection rates of approximately 0.6%, which was deemed unacceptable, while other surgical and medical locations had more acceptable rates around 0.2% (range: 0.19–0.21%).

Information regarding the occupational status (e.g., professional degree, level of training) of personnel (“phlebotomists”) collecting the (rejected) blood specimens was obtained, such information was available for 2709 (79.1%) of 3425 specimens (Table 3). The vast majority of rejected specimens was collected by registered nurses (RNs), drawing 2320 (85.64%) specimens. In contrast, laboratory phlebotomy personnel only drew 109 (4.02%) rejected specimens. Registered nurses also had the highest median number ($n = 3$) of

TABLE 3. Specimen Rejection by Type of Healthcare provider Collecting Specimen (e.g., Laboratory Phlebotomist, Registered Nurse, etc.)

Phlebotomist type	Rejected specimens (N = 2709)	Percentage (%) rejected specimens	Median # per individual
Registered nurse	2320	85.64	3
Patient care technician	186	6.87	1
Laboratory phlebotomist	109	4.02	2
Licensed practical nurse	47	1.73	1
Other*	47	1.73	2

*Other includes healthcare providers such as house staff, physician assistant, etc.

Data included here are based on available information regarding personnel collecting specimens.

rejected specimens per individual phlebotomist. The only statistically significant difference in types of rejection between various types of phlebotomists was the fact that laboratory phlebotomists had a much higher ratio of clotted to hemolyzed specimens compared to other phlebotomist groups ($P < 0.001$). Across all clinical units surveyed in this study, there was a noticeable variation in percentage of specimens collected by a specific type of phlebotomist. For example, in the ED

a higher number of specimens that were ultimately rejected were collected and submitted by patient care technicians and other types of practitioners, while rejected specimens from patients located on the medical, surgical, and telemetry units were more commonly collected and submitted by laboratory phlebotomists.

Furthermore, a subset of patients was identified for whom multiple rejected specimens were identified to be submitted in consecutive order of collection and/or close timely proximity. Two hundred and forty-eight patients had more than one clotted specimen, and 85 of these patients had more than two (range 3–23). Of patients with more than two clotted specimens, 60.7% were located in the NICU; this unit also had the highest overall rate of specimen rejection for issues related to clotting of specimens. Overall, 151 patients had more than one hemolyzed specimen, and 30 of these patients had more than two (range 3–11). Among patients with more than two hemolyzed specimens, 36.7% were located in the CICU, 20.0% were in the ED, and 16.7% were located in the MICU. There were 147 patients who had specimens rejected for both clotting and hemolysis. Of these patients, 27.2% were located in the ED, which was the most common location for submission of specimens that were ultimately rejected by the laboratory for the above-referenced indications.

The reason for specimen rejection varied predictably according to the tests ordered and specimen collection tube/anticoagulant used in collection tube. The 3411 rejected specimens corresponded to 4170 individual tests. The most common tests canceled for the reason of a clotted sample were complete blood count (CBC) with differential, capillary blood gas samples, and CBC without differential. Of clotted specimens, 64% were identified with use of serum separator tubes and 28.1% of clotted samples submitted for ABG analysis used either a capillary tube or syringe with no anticoagulant. In contrast, the most common tests canceled for hemolysis were found in samples submitted for prothrombin time, partial thromboplastin time, and magnesium level. Of hemolyzed specimens, 59.8% were collected in a citrate tube, while 32.0% were collected in an EDTA tube.

A number of other variables also may have contributed to specimen rejection in a less straightforward manner. There was a significant difference in the number ($P = 0.001$) and proportion ($P < 0.001$) of specimens rejected between various months of the year, with the highest numbers of specimens rejected during the months of January, March, and April, and the highest rejection rates being seen during the months of November, December, and August. There was also a significant difference in the number of specimens

rejected per day of week ($P < 0.001$), with the most specimens rejected on Thursdays and Tuesdays. Additionally, the number of specimens rejected differed significantly by hour of day ($P < 0.001$), with the highest numbers for rejected specimens seen between 2:00 a.m. and 5:00 a.m. The reasons for the differences across months, days, and/or hours of day were not clear, although fluctuations in specimen volume were likely an independent variable contributing to the disparity between days and hours when specimen rejection rates were highest. Finally, we analyzed the impact of time delays in specimen submission from collection to receipt by the laboratory. The interval between specimen collections and receipt in the laboratory did not vary significantly between the different types of specimen rejection, location of specimen draw, or phlebotomy personnel ($P > 0.05$ for all variables mentioned here).

The overall, average rate of specimen rejection between July 2014 and July 2015 was 0.73% (range 0.63–0.80%). There was no statistically significant difference between the average specimen rejection rates for the 2013–2014 (0.74%) and the 2014–2015 (0.73%) time periods ($P = 0.59$).

DISCUSSION

Overall, this study underscores the need for laboratories to investigate their own specimen rejection patterns. While some previous single-institution studies of rejection patterns have reported that hemolysis is the predominant cause for specimen rejection (6, 10, 14, 17), others have found a preponderance of clotted specimens (11, 14), specimens with insufficient volume (12), and labeling irregularities (18). Yet other laboratories have reported a significant number of specimens in three or more of these categories (2, 9, 11, 15). At JHBMC, clotted and hemolyzed specimens had nearly equal prevalence during the year of this investigation, together comprising 94.6% of rejected specimens. This also indicates that rates for other types of preanalytical errors, including mislabeling and insufficient volume at our institution are low. These findings suggest that our barcode labeling system and menu of test requires do provide adequate support for labeling and quantity, allowing us to focus all of our remediation efforts on decreasing the problematic rates of clotting and hemolysis.

Second, this study highlights the fact that specimen acceptability issues can be heterogeneous even within a single hospital. While a few studies have tabulated locations of draw for rejected specimens (6, 15, 16), none have evaluated differences beyond broad inpatient, outpatient, or emergency categories. The more

granular analysis of rejection rates across the various units at our institution allowed us to highlight large differences in rejection rates in different units, even beyond the well-established prevalence of specimen rejection in the ED (6, 20). At our hospital, 10 patient care areas were identified to be responsible for almost 85% of all rejected specimens during 1 year of investigation. Even if these 10 patient care areas could only decrease their rejections by half, our hospital would be able to meet its target rate for specimen acceptability. Moreover, the types of specimens rejected varied per unit. While the NICU predominantly had difficulties with clotting, the ED, CICU, MICU, and telemetry units disproportionately struggled with hemolysis. These findings allow us to tailor our interventions to patient care areas and units most in need of improvement with further emphasis on the most common reasons for specimen rejection each of these areas/units incurs.

Third, this study emphasizes the key role of nonlaboratory personnel in determining specimen acceptability. Although the CAP considers specimen acceptability to be a laboratory quality measure, we found that many of the preanalytic variables that contribute to a specimen being rejected occur outside the laboratory. Several previous studies have also described that rejected specimens are more likely to be drawn by nonlaboratory personnel (6, 9, 17, 24, 25), therefore indicating that specimen rejection is a quality measure that is not solely an issue for laboratories, but should be viewed as a complex, multidisciplinary quality measure for healthcare institutions. Our study confirms these findings, with only 4% of rejected specimens at JHBMC being drawn by laboratory phlebotomy staff, whereas 85.6% of specimens being drawn by registered nurses. Therefore, finding an intervention and solution to this problem will require collaboration between the laboratory, nursing staff, and other hospital patient care provider groups. It is important to recognize that, while registered nurses comprised the vast majority of nonlaboratory phlebotomists in this study, patient care technicians and licensed nurse practitioners also contributed to the specimen rejection problems, particularly in the ED. It will be essential to include all types of staff providing patient care in education efforts and/or interventions that attempt lowering specimen rejection rates in healthcare institutions.

Fourth, the results from this study suggest that several opportunities exist at our hospital/institution for solving the problem of specimen rejection. The data analysis for specimen rejections of patients with repeat rejected specimens suggests that a few patient characteristics may contribute to specimen rejection. The low

volume draws necessary for low/very low-birth-weight NICU patients certainly raises their risk of specimens being clotted samples, while a few other patients in other patient care areas may actually have an underlying medical condition or may receive treatment associated with a higher risk for a hemolytic condition. At the end, however, most of the rejected specimens, even those that were repeatedly rejections in certain patients, were closely linked to one or more of the following three factors: specimen clotting or hemolysis, location in emergency or ICU locations, and collection by nonlaboratory phlebotomy staff. Both clotting and hemolysis were previously in other studies described to be strongly linked to poor phlebotomy technique (2, 13). Moreover, studies described that continuing education in proper phlebotomy techniques for nurses in critical care locations is almost nonexistent (25, 26). Based on this evidence, coupled with the results and observation from our own investigation, we decided to initiate newly developed phlebotomy education modules for healthcare practitioners involved in specimen collection in the patient care areas identified in this study. We believe that this type of intervention is (hopefully) an efficient first step in resolving quality issues related to specimen rejection. We initially determined that in case of no significant improvement of specimen rejection rates, we should further actively collaborate with various staff involved in patient specimen collection in order to determine whether additional changes in phlebotomy procedure guidelines, equipment, or restructuring of the phlebotomy workforce could help improve acceptability.

Based on the results of this study, we propose a simple three-step algorithm for investigating specimen acceptability (Fig. 2). First, collect all available data regarding rejected specimens from the laboratory information system. Essential variables should include reason for rejection, patient location, phlebotomist identity, container characteristics, and time, but other institutionally relevant factors need to be included as well. Second, analyze specimen rejection data at the most granular level possible. It is important to comprehensively consider all available details to identify which variables contribute most significantly to specimen rejection within a given institution. Finally, target the most significant factors contributing to high specimen rejection rates for designing the approach to remediation. Design an efficient intervention plan that is tailored to specific institutional problems and characteristics and solicit the input from patient care providers outside the laboratory. By following this simple framework, our institution was able to identify the primary causes for our elevated specimen rejection rate and design a customized educational intervention.

Fig. 2. Proposed approach and algorithm for investigating the causes of specimen acceptability and targeting appropriate interventions.

The described intervention of using newly developed phlebotomy education modules for healthcare practitioners involved in specimen collection was initiated in July 2014 with the support of RN team leaders from the ICUs, the ED, and the Education Department in our hospital. While we continued to monitor the overall specimen rejection rates, we noticed that rates had decreased by October 2014 to 0.67% from initial average of 0.74% from the previous year. However, during the following months we observed a fluctuation of rejection rates, with a range from 0.63% to 0.80%. Overall, the average specimen rejection rate during the 12 months following the initial intervention was 0.73%. The difference between the two time periods studied was not statistically significant ($P = 0.59$). While educational interventions have shown here and in other studies to improve specimen rejection rates, the long-term sustainable effect of such intervention may seem questionable, and would therefore require continued educational intervention on an annual basis or even more frequently. Such approach may result in a significant burden to staff, workflow practices, and the education departments in hospitals. As mentioned above, we proposed additional, more systematic interventions in case of a nonsustained/nonsignificant effect of the

educational intervention. As proposed, such systematic interventions could include changes in phlebotomy procedure guidelines, equipment, or restructuring of the phlebotomy workforce, i.e., have phlebotomy team collect specimens throughout the hospital at all critical locations, therefore minimizing the volume of specimens collected by other healthcare staff. Other systematic interventions could include use of larger gauge needles for venipuncture, use of straight needle phlebotomy technique, use of partial vacuum collection tubes, avoiding use of syringes or draws through i.v. catheters. In this respect, one study described the success of reducing specimen rejection rates and hemolysis of specimens in the ED setting, by requiring experienced ED nurses to only collect blood via venipuncture instead of intravenous catheters (27). Another study investigated mixing techniques and vacuum blood collection tubes, and found that instant mixing may introduce interference for certain tests susceptible to hemolysis (28). Additional studies will be needed to further evaluate the effects of systematic changes such as use of straight needle venipuncture or use of partial vacuum tubes as systematic interventions to reduce hemolysis and specimen rejection rates.

In conclusion, the comprehensive analysis of specimen acceptability criteria and specimen rejection detailed in this study emphasized that specimen rejections for various reasons are a continuous challenge for hospitals and other laboratories. Detailed analyses of specimen rejection rates and related issues, allowed us to formulate an inter-disciplinary and efficient plan targeted to decrease specimen rejection rates at our institution. While we experienced an immediate decrease in rejection rates initially following the educational intervention, we found during continued monitoring of rejection rates for a 12-month period no sustained significant decrease in specimen rejection rates. Educational interventions, as described previously, may have to be repeated at time to remain effective; furthermore, we believe that the chosen approach, including future systematic interventions as described above, could be useful for our own institution as well as to other laboratories that are attempting to solve similar issues related to monitoring and ultimately decreasing high specimen rejection rates.

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