

# Specimen rejection in a high-throughput TB laboratory: A descriptive study

**To the Editor:** In 2015, the South African (SA) National Health Laboratory Service (NHLS) reported an 8.3% (220 000/2.65 million) national tuberculosis (TB) sputum rejection rate.<sup>[1]</sup> Patients with rejected specimens will likely have a delayed diagnosis or remain undiagnosed. Regardless, local studies have yet to be performed to evaluate the reasons and magnitude for specimen rejection related to TB investigations. Areas with high rejection rates need to be identified in order to implement pragmatic quality improvement training interventions.

This descriptive study evaluated retrospective data spanning 2 years (1 March 2021 - 28 February 2023) on the reasons for rejecting specimens submitted to the NHLS Green Point complex TB laboratory. Monthly rejection rates were determined by dividing the number of tests rejected by the total performed. Reasons for rejecting a specimen, among others, included: information on the container does not match that on the specimen, no request form received with the specimen, specimen unsuitable (for example, saliva), container empty on arrival, volume insufficient, container not labelled, leaking, or specimen not received with the laboratory request form.<sup>[2]</sup> Duplicate specimen rejections for different TB-related tests from the same container were excluded from the analysis. Rejection cases were plotted according to the healthcare institution where the specimen was submitted, using ArcGISPro version 2.0 (Environmental Systems Research Institute, USA).

Ethical approval with a waiver for informed consent was obtained from the Human Research Ethics Committee of Cape Town University (ref. no. 270/2023).

The 24-month evaluation showed a rejection total of 13 396 in the Western Cape Province, SA, among 588 116 TB-related tests. The rejection rate varied from 3.1% (612/19 511) in March 2021 to 1.0% (252/25 282) in August 2022 (Fig. 1), with an average of 2.3% (558 cases/month) over the 2 years. Leaking specimen containers were the leading cause of TB specimen rejection, at 60.9% (8 157/13 396), followed by the specimen container being empty at 14.2% (1 903/13 396) and insufficient specimen volume at 7.9% (1 052/13 396), respectively (Fig. 2). Geographical maps showed a potential high rejection area

among the Cape Metropole's Mitchells Plain, Tygerberg and Eastern sub-health districts (Fig. 3). Further studies will focus on ascertaining the number of specimens

processed in these specific areas with possible enhanced training of TB healthcare workers for appropriate specimen collection to reduce rejection rates.

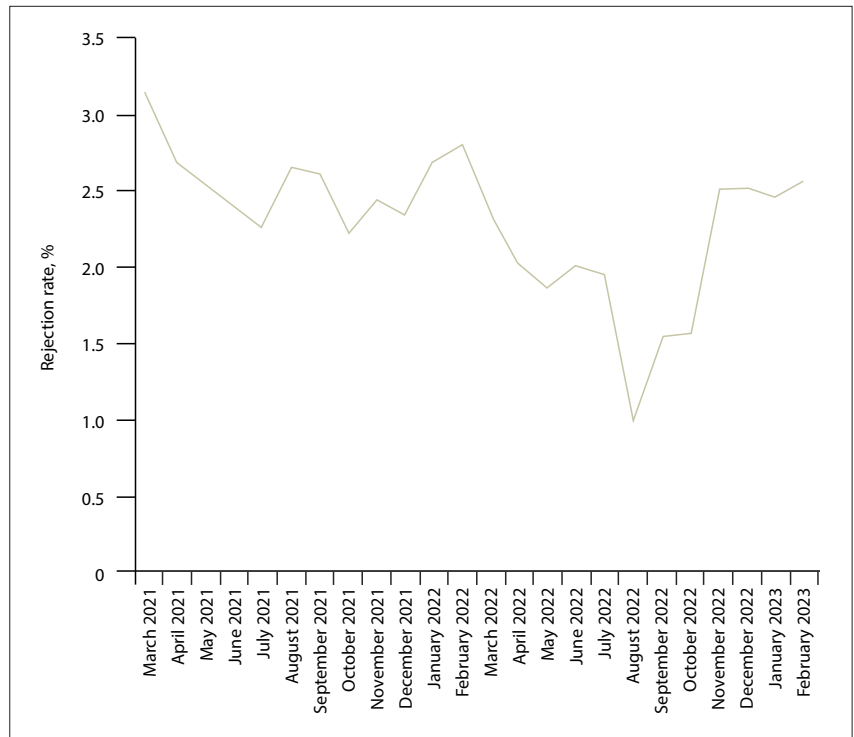


Fig. 1. Rejection rates of specimens submitted for tuberculosis investigation to Green Point laboratory between 1 March 2021 and 28 February 2023 in the Western Cape Province, South Africa.

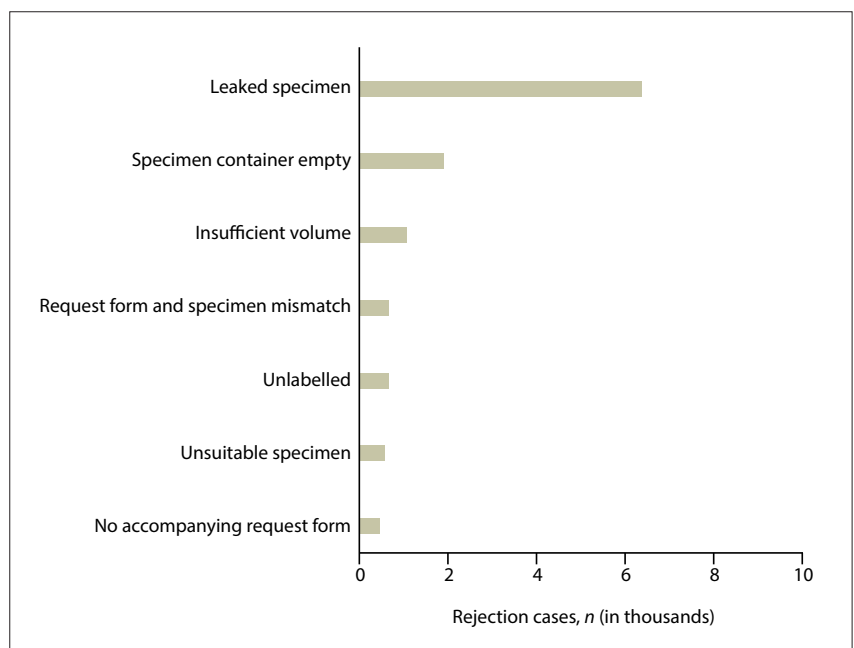


Fig. 2. Reasons and numbers of clinical specimens rejected for tuberculosis investigation.

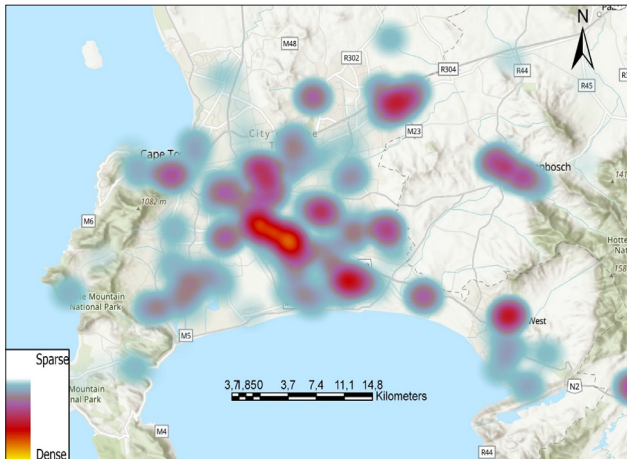


Fig. 3. Spatial mapping of the 24-month investigation period (1 March 2021 - 28 February 2023), indicating rejected specimens plotted according to the healthcare institution that submitted the specimen. The National Health Laboratory Service Green Point TB laboratory receives specimens from 53 hospitals and 170 primary healthcare facilities in and around Cape Town. In total, 8 573 rejection cases were noted among the eight health districts during the 2-year investigation period in Cape Town, South Africa. Rejection cases (n) as per subdistrict: Eastern (1 976); Khayelitsha (643); Klipfontein (844); Mitchells Plain (1 273); Northern (753); Southern (767); Tygerberg (1 197); and Western (1 120).

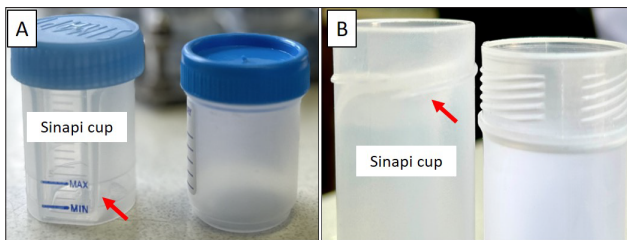


Fig. 4A and B. Elements of the Sinapi container design. A: Clear volumetric indicators on the specimen container to encourage sufficient specimen collection. B: The lid uses a three-thread design to optimise alignment, allowing for a 90° once-off twist or close ergonomic action with a leak-proof seal. Red arrow: Sinapi container with designed features.

The rejected specimens for TB investigation are not only a financial burden on the healthcare system but a potential missed opportunity to diagnose *Mycobacterium tuberculosis* complex in a patient. Although the average rejection rate of 2.3% over the 2 years was below the accepted 3% standard for specimen rejection,<sup>[3]</sup> submitting an empty container (14.2%) or not labelling specimens (4.7%) is avoidable. In this regard, collaboration with local laboratories can be vital in supporting healthcare institutions with appropriate specimen collection training and surveillance of rejection rates to ensure timely interventions. In addition, the current study revealed that TB specimen leakage (60.9%) remains a significant impediment, and can be addressed with container design improvement (Fig. 4A and B). All specimens were processed and cultured at the National Health Laboratory Service, Green Point laboratory, Cape Town, South Africa.

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**Conflict of interest.** Dr Magda Botha is employed by Sinapi Biomedical, but received no financial incentive to collaborate in the research.

**Data sharing.** The data supporting this study's findings are available from the corresponding author, CJO, upon reasonable request upon NHLS institutional approval from a controlled access repository.

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