


# Diagnosis of the leprosy laboratory care network in Regional Health Department XV, São José do Rio Preto, São Paulo, Brazil\*


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Fernanda Modesto Tolentino Binhardi<sup>1</sup> –  orcid.org/0000-0002-2172-6594

Susilene Maria Tonelli Nardi<sup>1</sup> –  orcid.org/0000-0001-8793-8437

Flávia dos Santos Patine<sup>2</sup> –  orcid.org/0000-0001-6103-2477

Heloisa da Silveira Paro Pedro<sup>1</sup> –  orcid.org/0000-0002-5088-2510

Janaína Olher Martins Montanha<sup>1</sup> –  orcid.org/0000-0003-1710-2225

Milena Polotto de Santi<sup>1</sup> –  orcid.org/0000-0002-6419-7987

Naiara Cristina Ule Belotti<sup>1</sup> –  orcid.org/0000-0002-4047-2171

Vania Del'Arco Paschoal<sup>3</sup> –  orcid.org/0000-0002-6047-5345

<sup>1</sup>Instituto Adolfo Lutz, Núcleo de Ciências Biomédicas, São José do Rio Preto, SP, Brazil

<sup>2</sup>Grupo de Vigilância Epidemiológica 29, Programa Regional de Controle da Hanseníase, São José do Rio Preto, SP, Brazil

<sup>3</sup>Faculdade de Medicina de São José do Rio Preto, Departamento de Enfermagem em Saúde Coletiva e Orientação Profissional, São José do Rio Preto, SP, Brazil

## Abstract

**Objetivo:** To present the situational diagnosis of the leprosy laboratory reference network in the region of São José do Rio Preto, SP, Brazil. **Methods:** This was an evaluation study with a descriptive design. The data were collected by means of an online form filled in by those in charge of the leprosy program in 2018. **Results:** All 102 municipalities that make up the region provided the requested data, 82.4% (84/102) requested slit-skin smear microscopy and of these 68 received training. Of the total, 11.7% sent slit-skin smears to other laboratories outside the reference network. Only 57.8% (59/102) requested a biopsy, of these 47 had a doctor responsible for taking the biopsy sample and 31 did not send biopsy samples for analysis in the reference network. Lack of an adequate room, few trained professionals, absence of material for transportation and absence of printed test requisitions were described as aspects that hinder leprosy case diagnosis in the region. **Conclusion:** The laboratory network is fragile and needs to be restructured.

**Keywords:** Leprosy; Public Health Laboratory Services; Health Services Research; Public Health; Health Management.

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## Correspondence:

**Fernanda Modesto Tolentino** – Instituto Adolfo Lutz, Rua Alberto Sufredini Bertoni, No. 2325, Vila Maceno, São José do Rio Preto, SP, Brazil. Postcode: 15.060-020

E-mail: fernanda.tolentino@ial.sp.gov.br

## Introduction

Leprosy is caused by *Mycobacterium leprae* and belongs to the group of neglected tropical diseases.<sup>1</sup> It is a communicable disease which develops slowly, manifests itself through dermatological and neurological signs and symptoms, caused by pathological and immunological processes occurring directly in peripheral nerves.<sup>2,3</sup>

The Ministry of Health defines a leprosy case as being when there are lesion(s) and/or area(s) of skin with changes in heat sensitivity and/or pain sensitivity and/or touch sensitivity; or thickening of the peripheral nerve, associated with sensitivity and/or motor and/or autonomic changes; or presence of *M. leprae* bacillus in slit-skin smears or skin biopsies.<sup>4</sup>

*Health workers lack information about the network of laboratories in their catchment area equipped to provide suspected and confirmed leprosy cases with quality tests and/or refer the respective samples to a reference laboratory.*

Slit-skin smear microscopy continues to be the only laboratory test required by the Ministry of Health and provided by the Public Health network. It is a quick and low-cost test, has good accuracy for classifying the clinical form of the disease and, therefore, assists with defining the treatment regimen.<sup>5</sup> Biopsy is of great relevance when it is not possible to perform leprosy differential diagnosis using slit-skin smear microscopy, or when clinical procedures do not provide elucidation;<sup>6</sup> biopsy can also be useful for diagnosing the difference between reversal reaction and relapse.<sup>7</sup>

Other laboratory tests, besides biopsy and slit-skin smear microscopy, contribute to differentiating leprosy from other diseases with similar signs and symptoms. Serological tests (PGL-1) assist with precise diagnosis of the disease and, when associated with clinical analysis, assist with the decision as to the most adequate form of treatment, avoiding possible cases of treatment failure, drug resistance and/or reinfection. New leprosy diagnosis methods, in the areas of Molecular Biology and Genetics, are being studied and

tested; however, possibly because they cost more and require specialized technical staff, these tests are not available in public health services - except for some of them in a few reference centers.<sup>8</sup>

Health workers on the front line of health care, whether in primary health care centers or in reference centers, apart from high staff turnover, lack information about the network of laboratories in their catchment area equipped to provide suspected and confirmed leprosy cases with quality tests and/or refer the respective samples to a reference laboratory.

The objectives of this study were to present the situational diagnosis of the leprosy laboratory network in the area covered by the São José do Rio Preto Regional Health Department in São Paulo State, Brazil, and to propose the updating of a laboratory test sample collection and sending flow from municipal leprosy care services to the reference laboratory.

## Methods

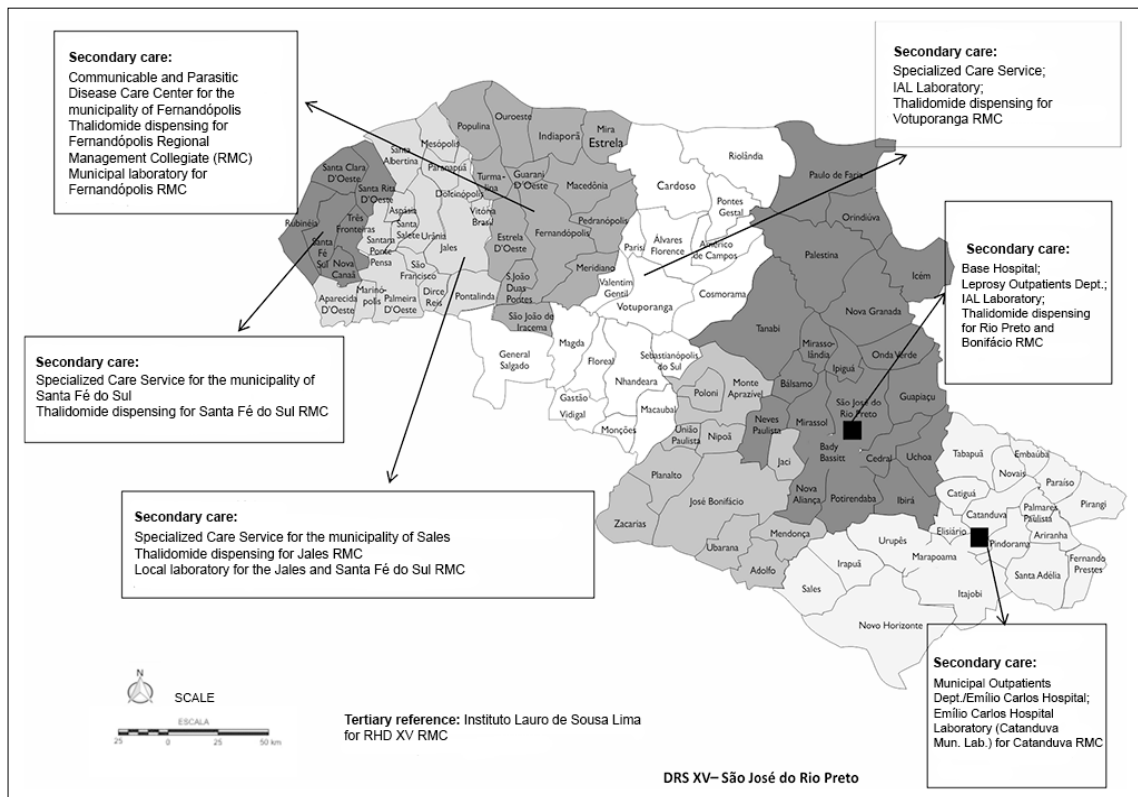
This is a health service evaluation study with a descriptive design, based on situational investigation of the São José do Rio Preto Regional Health Department (RHD XV) care network for people suspected or confirmed as having leprosy.

RHD XV is one of 17 regional health departments of São Paulo State and is comprised of Epidemiological Surveillance Group 29 – São José do Rio Preto (ESG-29) – and Epidemiological Surveillance Group 30 – Jales (ESG-30) –, which cover 67 and 35 municipalities, respectively, with a total population of 1,557,237 inhabitants in 2018.

The leprosy program is one of the programs developed by the municipalities belonging to ESG-29 and ESG-30. Between 2010 and 2018, they treated 885 and 675 people with leprosy, respectively.

The leprosy care network, defined in collegiate meetings and put into operation by the 'Alexandre Vranjac' Epidemiological Surveillance Center State Leprosy Control Program, is shown in Figure 1.

The data were collected between January and March 2018, using an online form via the Google Forms application, containing questions about the patient care dynamics and flow at health services, sample collection, storage and transportation, follow-up of diagnosed leprosy cases and training of health workers involved.



**Figure 1 – Map of the leprosy care network in Regional Health Department XV, São José do Rio Preto, São Paulo State, 2018**

A message was sent by email containing the link to the form to those in charge of the leprosy program or epidemiological surveillance in each of the 102 municipalities belonging to RHD XV, requesting them to fill it in. The completed form was the study’s main source of data. Telephone calls were made to the municipalities that did not fill in the form, emphasizing the importance of their doing so.

The data obtained via the online form were imported to an Excel spreadsheet and, once they had been organized and consolidated, the absolute and relative frequencies and the mean and standard deviation of the variables were analyzed with the aid of the statistical computer program Epi Info, version 7.2.2.

The study project was approved by the Instituto Adolfo Lutz/São Paulo State Health Department Research Ethics Committee: Opinion No. 2.101.044, issued on June 5<sup>th</sup> 2017. All participants signed a Free and Informed Consent form.

## Results

Answers were received from health professionals from all 102 municipalities belonging to RHD XV. The results showed that 17.6% (18/102) of the municipalities did not request slit-skin smear microscopy to confirm results. Among the health professionals from the 84 (82.4%) municipalities that did request slit-skin smear microscopy, 16 replied that they had not had technical training for collecting samples. Of the 59 (57.8%) municipalities with health workers who requested biopsies, 47 had a doctor responsible for collecting the samples which were then sent for analysis in laboratories in the region; 12 requested biopsies but did not have a doctor responsible for this and did not inform where they referred the patient to in order for the sample to be collected (Table 1). The difficulties listed by the municipalities in requesting tests and/or collecting samples are shown in Table 1.

Of the 43 (42,2%) municipalities that did not request biopsies and did not collect samples for biopsies, 25 answered that they referred patients to other health services without respecting the RHD XV leprosy care network; 18 municipalities did not request and/or did not collect material for biopsy (Table 2).

Table 2 shows the distribution of the number of municipalities that followed the protocol for slit-skin smear sample collection sites, form of sending/transport, time between collection and sending and sample packaging.

The data shown in Table 3 reveal that 70.6% (n=72) and 45.1% (n=46) of the municipalities followed the laboratory network defined by RHD XV for slit-skin smear microscopy and for biopsy, respectively. When asked about their knowledge of serological tests (PGL-1), 27 (26.5%) municipalities answered that they knew about the test, while only 2 of them requested it, possibly requesting it to be performed at the Instituto Lauro de Souza Lima tertiary reference service in Bauru, SP. With regard to molecular biology tests (Polymerase Chain Reaction – PCR), only 13 (12.8%) had knowledge of the existence/usefulness/indication of these tests for leprosy; none of the municipality health professionals requested PCR tests.

Regarding the characteristics of care for leprosy cases and their intrahousehold contacts after laboratory tests were performed, 37 made contact by telephone and household visits, 27 only made household visits and 17 only made telephone contact. Three municipalities reported other forms of making contact with case households: personally, at the health center (n=1); by telephone, household visit and medical consultation (n=1); and visit and a reminder letter (n=1).

In 69.6% (71/102) of the municipalities, there was a doctor to provide care and/or follow-up for cases at the health center; in 84.3% (86/102), those in charge carried out dermatology/neurology examinations on intrahousehold contacts; and in 95% (97/102), BCG (Bacillus Calmette-Guérin) vaccine was administered to intrahousehold contacts.

The study produced a poster (Figure 2), which was sent to all the leprosy patient care services for educational purposes and to standardize services provided by the care network, showing the location of municipal and regional reference services, defining the flow for test referrals to be provided at health centers and standardizing the main procedures for sending samples for laboratory testing.

**Table 1 – Laboratory tests requested for leprosy, support material and health worker training in the municipalities belonging to Regional Health Department XV (N=102), São José do Rio Preto, São Paulo State, 2018**

| Variables  | Slit-skin smear microscopy |      | Biopsy |      |
|--|----------------------------|------|--------|------|
|  | N                          | %    | N      | %    |
| <b>Municipalities that requested the test</b>  | 84                         | 82,4 | 59     | 57,8 |
| <b>Municipalities that had material for collecting slit-skin smears and biopsies</b> | 83                         | 81,4 | –      | –    |
| <b>Municipalities that had a staff member trained in collecting slit-skin smears</b> | 68                         | 66,7 | –      | –    |
| <b>Municipalities that had a doctor responsible for collecting biopsy samples</b>    | –                          | –    | 47     | 46,1 |
| <b>Difficulties in sending samples or performing test in relation to:</b>            |                            |      |        |      |
| Transport/driver   | 20                         | 19,6 | 4      | 3,9  |
| Transportation material  | 3                          | 2,9  | –      | –    |
| Printed requisition form   | 3                          | 2,9  | –      | –    |
| Trained professional   | 3                          | 2,9  | 37     | 36,3 |
| Room suitable for sample collection  | –                          | –    | 6      | 5,9  |
| Two or more of the above difficulties  | 4                          | 3,9  | 16     | 15,6 |
| Reported not having difficulties   | 51                         | 50   | 21     | 20,6 |
| Did not answer   | 18                         | 17,6 | 18     | 17,6 |

**Table 2 – Number of municipalities (N=84) that followed the leprosy slit-skin smear sample protocol for collection site, form of sending/transport, time between collection and sending and sample packaging, Regional Health Department XV, São José do Rio Preto, São Paulo State, 2018**

| Variables  | N  |
|--|----|
| <b>Site of skin smear collected</b>  |    |
| Earlobe, elbow and lesion  | 65 |
| Earlobe and elbow  | 11 |
| Earlobe and lesion   | 2  |
| Other  | 6  |
| <b>After material is collected, the slide is fixed (Bunsen burner, lighter or similar)</b>   |    |
| Yes  | 71 |
| No   | 13 |
| <b>Time elapsed between collecting sample and sending it to the laboratory</b>   |    |
| 1 - 2 days   | 81 |
| More than two days   | 3  |
| <b>Storage</b>   |    |
| Slide holder   | 74 |
| Bench  | 6  |
| Aluminum foil  | 2  |
| Carton box   | 2  |
| <b>Transportation and storage are done using a hard box and slide holder identified with complete patient data and requesting unit</b> |    |
| Yes  | 82 |
| No   | 2  |

## Discussion

When delving into the dynamics of collecting, sending and receiving samples and reading and reporting on laboratory tests for leprosy, especially slit-skin smear microscopy and biopsy, the study found a structured laboratory network in the region, although it showed logistic weakness with regard to its effective use and technical up-to-dateness of health professionals.

Laboratory services should be organized in a manner coherent with Brazilian National Health System (SUS) decentralization, hierarchization and regionalization guidelines, so as to provide resolute capacity to its different levels of care complexity, i.e. primary, secondary and/or tertiary.<sup>9</sup>

Ministry of Health Ordinance GM/MS No. 149, dated February 3rd 2016, provides the regulatory framework for the leprosy Health Care Network and establishes that the control of this endemic disease should be based

on early diagnosis, timely treatment of all diagnosed cases, prevention and treatment of disabilities and surveillance of household contacts.<sup>4</sup>

Diseases caused by mycobacteria affect millions of people all over the world. Considering the global prevalence and incidence of leprosy, infectious agent transmission control and prevention objectives and targets are hard to achieve in current times.<sup>10</sup> Besides clinical care, laboratory support is an important aspect of surveillance and diagnosis, serving to confirm and classify cases, monitor treatment and antimicrobial resistance, as well as control of intrahousehold contacts.

In the region we studied, leprosy had reached elimination levels in 2008, with fewer than 10 cases per 100,000 inhabitants being notified.<sup>11</sup> Not with standing, the result achieved requires even more attention, since when a disease begins to have a low number of cases and the care network and health worker expertise tend

**Table 3 – Conformity of municipalities when sending slit-skin smear and biopsy samples to test for leprosy, according to reference laboratory, Regional Health Department (RHD) XV, São José do Rio Preto, São Paulo State, 2018**

| RHD XV reference laboratories                    | In conformity with RHD XV network | Not in conformity with RHD XV reference network | Sent to other laboratory not part of RHD XV reference network | Did not request and/or did not reply <sup>a</sup> | Total |
|--|-----------------------------------|---|---|---|-------|
|  | N                                 | N   | N   | N   | N     |
| <b>Slit-skin smear microscopy</b>                |                                   |   |   |   |       |
| Instituto Adolfo Lutz – IAL                      | 41                                | –   | 2   | 5   | 48    |
| Emilio Carlos Hospital Laboratory, Catanduva, SP | 16                                | 1   | –   | 2   | 19    |
| CYTOS Laboratory, Fernandópolis, SP              | 5                                 | 2   | –   | 6   | 13    |
| Jales-SP Laboratory                              | 10                                | 7   | –   | 5   | 22    |
| <b>Biopsy</b>                                    |                                   |   |   |   |       |
| Instituto Adolfo Lutz – IAL                      | 20                                | 3   | 17  | 8   | 48    |
| Emilio Carlos Hospital Laboratory, Catanduva, SP | 15                                | 1   | –   | 3   | 19    |
| CYTOS Laboratory, Fernandópolis, SP              | 8                                 | –   | –   | 5   | 13    |
| Jales-SP LaboratorySP                            | 3                                 | 2   | 8   | 9   | 22    |

a) Slit-skin smear and Biopsia: 18 (17.6%) municipalities do not perform and/or do not collect; 07 (6.9%) did not inform where they send the biopsy sample to.

to dissipate, diagnosis becomes increasingly late and manifestations of the disease become more serious.

The three key signs for leprosy diagnosis, as per the national guidelines for leprosy control, are (i) area or patch of skin with hypesthesia and/or (ii) changes to nerve function and/or (iii) positive slit-skin smear microscopy.<sup>12</sup> When these three signs are present, diagnostic sensitivity reaches 97%.<sup>8</sup> Clinical dermatological and neurological examination, positive slit-skin smear microscopy and, when possible, confirmatory biopsy, continue to be paramount for defining diagnosis of leprosy.

Slit-skin smear microscopy and biopsy are considered to be straightforward and low-cost tests. This simplicity is evident when compared to the complexity of other sophisticated and high-cost laboratory techniques performed by well-trained staff.<sup>13,14</sup>

In the São José do Rio Preto region, 19% of the municipalities did not have health professionals trained to collect slit-skin smear samples and over 50% did not have a doctor responsible for collecting samples for biopsies. Within this context, the role of municipal, regional, state and federal health service managers takes on special relevance and should be

carried out jointly with universities specialized in this theme, in the sense of providing continuing education. Training leaves health professionals more secure to make decisions and conclude leprosy diagnosis.<sup>15,16</sup>

Despite the obligatory presence of a specialist doctor when following-up on diagnosed cases, the study indicated that 59.8% of health centers did not comply with this criterion. It is important to highlight that health teams should be complete and structured so as to provide comprehensive health care to people with leprosy and their household contacts, and, if there is no doctor to provide case follow-up, cases should be referred to the nearest service where the patient can be cared for correctly.

The interviewed health professionals reported making technical mistakes related to slit-skin smear microscopy, such as collecting fewer smears than recommended, not fixing the sample on the slide, inadequate storage and transportation. A study conducted in India proved the efficiency and importance of slit-skin smear microscopy and biopsy test results in conjunction with clinical characteristics, for obtaining conclusive diagnosis of cases.<sup>17</sup> Laboratory tests should follow defined protocols, right from collection of the sample through to the final technical result report.

# HANSENÍASE

## FLUXOGRAMA PARA ENCAMINHAMENTO DE EXAMES LABORATORIAIS

### Rede de Atendimento a hanseníase no DRS XV

**Atenção Secundária:**  
Centro de Atendimento às Doenças Infectocontagiosas e Parasitárias-CADIP para o município de Fernandópolis  
Dispensação de Talidomida para CGR de Fernandópolis  
Laboratório Municipal para CGR de Fernandópolis

**Atenção Secundária:**  
Serviço de Atendimento Especializado – SAÉ/CTA para o município de Santa Fé do Sul  
Dispensação de Talidomida para CGR de Santa Fé do Sul

**Atenção Secundária:**  
Serviço de Atendimento Especializado – SAÉ/CTA para o município de Jales  
Laboratório Local para CGR de Jales e Santa Fé do Sul

**Atenção Secundária:**  
Serviço de Atendimento Especializado – SAÉ/CTA para o município de Jales  
Laboratório Local para CGR de Jales e Santa Fé do Sul

**Atenção Secundária:**  
Serviço de Atendimento Especializado – SAÉ/CTA para o município de Jales  
Laboratório Local para CGR de Jales e Santa Fé do Sul

**Atenção Secundária:**  
Serviço de Atendimento Especializado – SAÉ/CTA para o município de Jales  
Laboratório Local para CGR de Jales e Santa Fé do Sul

**Atenção Secundária:**  
Ambulatório Municipal/Hospital Emílio Carlos  
Laboratório Hospital Emílio Carlos (Laboratório Municipal de Catanduva) para CGR de Catanduva

### DRS XV – São José do Rio Preto

**Atenção Secundária:**  
Serviço de Atendimento Especializado – SAÉ/CTA para o município de Jales  
Laboratório Local para CGR de Jales e Santa Fé do Sul

**Atenção Secundária:**  
Ambulatório Municipal/Hospital Emílio Carlos  
Laboratório Hospital Emílio Carlos (Laboratório Municipal de Catanduva) para CGR de Catanduva

## BACILOSCOPIA

**Raspado INTRADERMICO**  
LOD LOE CD CE  
(ou)  
LOD LOE CD L

Desenhar os círculos no lado contrário ao fosco com caneta de retroprojetor *preta/azul*.

Ponta fosca identificação do paciente (*lápida*)

Lâmina e Porta Lâminas de Plástico rígido com identificação do paciente em ambos. Temperatura ambiente.

**UNIDADE DE SAÚDE**

**SOLICITAÇÃO EXAME BACILOSCOPIA para Hanseníase**

**COLETA**

**FIXAÇÃO**

**ARMAZENAMENTO**

Transporte Caixa Rígida / Entregar IAL Rio Preto

Consultar no GAL resultado de Baciloscopia ou aguardar laudo.

**Referência Terciária:** Instituto Lauro de Souza Lima Bauru para CGR da DRS XV.

**Cadastro SADT\* / GAL\***  
Requisição preenchida com todas as informações

Fixar somente quando esfregaço estiver seco com Lamparina, Bico de Bunsen, Isqueiro ou chama.

Prazo máximo de 24 horas

## BIÓPSIA

**UNIDADE DE SAÚDE**

Coleta (médico) frasco estéril formol

Armazenamento Temperatura Ambiente

Transporte Caixa Rígida / Entregar IAL Rio Preto

Cadastro GAL\*

Requisição obrigatória preenchida \*\*

\*\*Requisição de exame anatomo-patológico obrigatória para encaminhar

### REQUISICÃO EXAME BACILOSCOPIA

SUS – SISTEMA ÚNICO DE SAÚDE  
SECRETARIA DA SAÚDE DO ESTADO DE SÃO PAULO

Nome da Unidade Requisitante: \_\_\_\_\_  
Nome do Município Requisitante: \_\_\_\_\_

**SOLICITAÇÃO DE BACILOSCOPIA DE RASPADO INTRADERMICO**

NOME COMPLETO \_\_\_\_\_ SEXO \_\_\_\_\_ PRONOME \_\_\_\_\_  
DATA DE NASCIMENTO \_\_\_\_\_ UF \_\_\_\_\_ BAIRRO \_\_\_\_\_  
CIDADE \_\_\_\_\_ UF \_\_\_\_\_ DATA DA COLETA \_\_\_\_\_

DIAGNÓSTICO  CONTROLE FÓRMULA CLÍNICA  REINICIAL \_\_\_\_\_

LOCALIZAÇÃO DA COLETA: \_\_\_\_\_ ASSINALE A LOCALIZAÇÃO DAS LESÕES:

DESCRIÇÃO DA LESÃO: \_\_\_\_\_

HIPÓTESES DIAGNÓSTICAS: \_\_\_\_\_

EXAMES HISTOPATOLÓGICOS ANTERIORES (DIAGNÓSTICO, DATA E RESULTADO): \_\_\_\_\_

NA SUSPEITA DE HANSENÍASE PREENCHER:  
TESTE DE SENSIBILIDADE: ( ) NORMAL ( ) DUVIDOSA ( ) ANEST ( ) REPOST ( ) TESTE ( ) SÓLID ( ) SÉR

TESTE DE OREILHA: ( ) POSITIVO ( ) NEGATIVO ( ) EM ANDAMENTO ( ) N.R.  
BACILOSCOPIA MECANASAL: ( ) POSITIVO ( ) NEGATIVO ( ) EM ANDAMENTO ( ) N.R.  
TESTE DE TÁBARA: ( ) POSITIVO ( ) NEGATIVO ( ) EM ANDAMENTO ( ) N.R.  
TESTE DE METZNER: ( ) POSITIVO ( ) NEGATIVO ( ) EM ANDAMENTO ( ) N.R.  
RETRABAMENTO: ( ) SIM ( ) NÃO ( ) EM ANDAMENTO ( ) N.R.

FINALIDADE DO EXAME ATUAL: ( ) DIAGNÓSTICO ( ) CONTROLE ( ) ALTA

Profissional Requisitante: \_\_\_\_\_ Responsável pelo exame: \_\_\_\_\_  
(nome completo e assinatura) (Carimbo e assinatura)

### REQUISICÃO EXAME BIÓPSIA

SECRETARIA DE ESTADO DA SAÚDE  
DISTRITO ADMINISTRATIVO  
Av. Dr. Carlos R. de Toledo, 111 - Jd. Santa Cruz, 13127-770 - São Paulo  
CENTRO DE PATOLOGIA  
REQUISIÇÃO DE EXAME ANATOMO-PATOLÓGICO

NOME: \_\_\_\_\_  
DATA DE NASCIMENTO \_\_\_\_\_ CNIS: \_\_\_\_\_  
EST. CIVIL: \_\_\_\_\_ SEXO: \_\_\_\_\_ RAÇA: \_\_\_\_\_ PROFISSÃO: \_\_\_\_\_  
PROFISSIONAL: \_\_\_\_\_ NACIONALIDADE: \_\_\_\_\_  
MÉDICO RESPONSÁVEL: \_\_\_\_\_ CRM: \_\_\_\_\_  
INSTITUIÇÃO: \_\_\_\_\_  
MATERIAL ENTREGUE: \_\_\_\_\_ DATA DA COLETA: \_\_\_\_\_  
DADOS CLÍNICOS: \_\_\_\_\_

DESCRIÇÃO DA LESÃO: \_\_\_\_\_  
HIPÓTESES DIAGNÓSTICAS: \_\_\_\_\_

EXAMES HISTOPATOLÓGICOS ANTERIORES (DIAGNÓSTICO, DATA E RESULTADO): \_\_\_\_\_

NA SUSPEITA DE HANSENÍASE PREENCHER:  
TESTE DE SENSIBILIDADE: ( ) NORMAL ( ) DUVIDOSA ( ) ANEST ( ) REPOST ( ) TESTE ( ) SÓLID ( ) SÉR

TESTE DE OREILHA: ( ) POSITIVO ( ) NEGATIVO ( ) EM ANDAMENTO ( ) N.R.  
BACILOSCOPIA MECANASAL: ( ) POSITIVO ( ) NEGATIVO ( ) EM ANDAMENTO ( ) N.R.  
TESTE DE TÁBARA: ( ) POSITIVO ( ) NEGATIVO ( ) EM ANDAMENTO ( ) N.R.  
TESTE DE METZNER: ( ) POSITIVO ( ) NEGATIVO ( ) EM ANDAMENTO ( ) N.R.  
RETRABAMENTO: ( ) SIM ( ) NÃO ( ) EM ANDAMENTO ( ) N.R.

FINALIDADE DO EXAME ATUAL: ( ) DIAGNÓSTICO ( ) CONTROLE ( ) ALTA

Profissional Requisitante: \_\_\_\_\_ Responsável pelo exame: \_\_\_\_\_  
(nome completo e assinatura) (Carimbo e assinatura)

Exames específicos como sorológicos (PGL-1), biologia molecular e resistência medicamentosa, entrar em contato com a referência terciária Instituto Lauro de Souza Lima - Bauru/SP – Tel.: (14) 3103-5700.

Figure 2 – Poster prepared and sent to all leprosy patient care services, for educational purposes and to standardize services provided by the Regional Health Department XV care network, São José do Rio Preto, São Paulo State, 2018

Performing slit-skin smear microscopy cannot be done in a self-taught manner, and it is essential to facilitate access to a standard operating procedure (SOP), to be used by health professionals to guide their daily practice.<sup>18</sup>

The health professionals interviewed, in each of the municipalities, reported diverse restrictions to collecting slit-skin smears and biopsy samples, such as there being no driver and/or vehicle, no printed requisition form, lack of an adequate room and packaging for transportation, as well as difficulties in sending samples. Leprosy services provided to SUS users, right from Primary Care through to reference services, need to be evaluated frequently with regard to quality standards being maintained.<sup>19</sup> Slit-skin smear microscopy and biopsy, when performed adequately, continue to be important laboratory tests for assisting with diagnosis,<sup>17</sup> as indicated by the World Health Organization (WHO), at least until new tests are incorporated into the SUS care network.<sup>20</sup>

This evaluation of the laboratory network concluded that almost a third of the municipalities did not follow the due criteria for slit-skin smears samples, and over half of them did not follow the criteria for biopsy samples. As such, continuing education, through information provided by epidemiological surveillance groups and even by reference laboratories, so as to keep municipal health service staff up to date, is an essential action to ensure that the care network works well.<sup>21</sup> This study demonstrated that the health professionals interviewed had little knowledge about serological and PCR tests, which is understandable, since they are tests that are not available in the laboratory network, despite being considerably referred to and discussed in the scientific community, according to published studies.

Moreover, diverse studies have highlighted immune response to the leprosy bacillus and use of serological tests to assist with classifying patients in order to define their treatment, treatment monitoring, risk of relapse, as well as for selecting contacts at greater risk of becoming ill.<sup>5, 22, 23</sup> Studies indicate that the association of different techniques can result in more precise diagnosis, especially in more serious cases. Serological tests, such as anti PGL-I, and molecular tests that use specific *M. leprae* genes as their target, have high sensitivity and specificity, and are indicated as important complementary tools for differential

diagnosis, classification of leprosy, identification of special cases of medication failure and, for cases with bacterial resistance to recommended medication, clinical and laboratory investigation at reference services.<sup>4,24-26</sup> Although restricted to research, adoption of these tests in the laboratory routine is indicated, principally in low-endemicity regions, given their contribution to epidemiological surveys<sup>24</sup> and to strengthening the patient care network.

As the results presented pointed to difficulties in gathering and sending material for testing, in the attempt to improve care for cases, we prepared educational material in the form of a poster, which was made available to health centers with the aim of instructing health professionals as to each stage of the laboratory test process. Of a self-explanatory nature and intended for practical consultation, the poster is aimed above all at services that request few tests and also those where there is high staff turnover whereby procedures are not adequately shared with new staff.

The biggest challenges to conducting this study, the aim of which was to understand the real situation of the laboratory care network in the area under the responsibility of Regional Health Department XV, were related to the delays in the questionnaires being filled in and returned by the professionals in the municipalities and, in some cases, absent or inconsistent answers. We suggest that these difficulties may have resulted from lack of knowledge about the subject on the part of some professionals recently taking on responsibility for the leprosy program in their municipality. Consideration must also be given to the urgency of actions in relation to acute diseases and/or diseases that cause epidemics, and the obligation to meet deadlines related to the diverse health care programs and lines of action existing in Brazil.

The establishment of an active and well-designed care network, with well-defined municipal and regional reference services, diversification of laboratory tests to achieve precise diagnosis and effective follow-up of cases, will contribute to the consolidation of the actions to eliminate leprosy in the state of São Paulo.

### Authors' contributions

Tolentino-Binhardi FM and Nardi SMT contributed to the study concept and design, analysis and interpretation



of the results, drafting and critically reviewing the contents of the manuscript. Patine FS, Pedro HSP, Montanha JOM, Santi MP, Belotti NCU and Paschoal VDA contributed to the study concept and design, drafting

and critically reviewing the contents of the manuscript. All the authors have approved the final version of the manuscript and are responsible for all aspects thereof, including the guarantee of its accuracy and integrity.

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Associate Editor: Lúcia Rolim Santana de Freitas - [orcid.org/0000-0003-0080-2858](https://orcid.org/0000-0003-0080-2858)