

SOS STOOLBOX

Simple One Step (SOS) stool processing method and Xpert MTB/RIF (Ultra) testing for the detection of *Mycobacterium tuberculosis* complex and rifampicin resistance

VARIABLES AND DATA
COLLECTION FORMS

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Minimum set of variables

In the table below, the minimum set of variables are listed that should be collected during the pilot implementation period of the SOS stool method for the detection of tuberculosis and rifampicin resistance.

Note that pilot implementation is meant to test the SOS stool method in the country's routine setting to learn more about the performance of the method in the context in which it will be used after scaling up to national level when the pilot has ended. A pilot implementation phase usually includes a limited number of health facilities and patients, and runs for a limited period of time.

Variable	Data type	Explanation	Data source
Unique participant code	Numerical	A numerical code that uniquely identifies each participant. In multicenter studies, this code should contain information about the center. E.g., first digit for the center, last three digits for the participant – the 5th participant in center 8 gets code 8005.	To be assigned by the study/ pilot team
Date of enrollment (or: date of first diagnostic visit)	Date	This is the date that the clinician assessed the participants because of his/her TB suggestive complaints.	Patient register
Participant date of birth	Date	If this date is not available, then alternatively age in months (for participants aged <1 year) or years (for older participants) can be collected.	Patient register
Participant sex	Categorical	Male/female.	Patient register
HIV status	Categorical	Positive/negative/unknown.	Patient register
Type of samples collected for laboratory diagnostic assessment	Categorical	Preferably pre-coded for most common types, e.g. 1=sputum 2= nasogastric aspirate 3=induced sputum 4=stool, etc.	Laboratory request form
Date of sample collection	Date	Ideally to be collected for each sample type.	Laboratory request form
Appearance of stool sample	Categorical	The Bristol stool chart can be followed to described the appearance of the stool. Otherwise, at least a differentiation should be made between solid (formed) and liquid (unformed).	Laboratory request form?
Stool Xpert test date	Date	Date that the stool sample was tested with Xpert.	Laboratory register, or obtained from the Xpert machine

Variable	Data type	Explanation	Data source
Stool Xpert test result	Categorical	Ideally not only detected/not detected/unsuccessful should be collected, but also specific test results; i.e., including bacterial load (trace/very low/low/medium/high) and rifampicin result for positive test results, and error codes.	Laboratory register, or obtained from Xpert machine
Repeat stool Xpert test result (in case the first test was unsuccessful)	Categorical	Ideally not only detected/not detected/unsuccessful should be collected, but also specific test results; i.e., including bacterial load (trace/very low/low/medium/high) and rifampicin result for positive test results, and error codes.	Laboratory register, or obtained from Xpert machine
Date of Xpert testing of sample types other than stool	Date	Should be added in case any other sample (than stool) from the same participant was tested.	Laboratory register, or obtained from Xpert machine
Other Xpert test result	Categorical	Ideally not only detected/not detected/unsuccessful should be collected, but also specific test results; i.e., including bacterial load (trace/very low/low/medium/high) and rifampicin result for positive test results, and error codes.	Laboratory register, or obtained from Xpert machine
Repeat other Xpert test result (if first test was unsuccessful)	Categorical	Ideally not only detected/not detected/unsuccessful should be collected, but also specific test results; i.e., including bacterial load (trace/very low/low/medium/high) and rifampicin result for positive test results, and error codes.	Laboratory register, or obtained from Xpert machine
Diagnosis	Categorical	Should contain information about the final diagnosis: TB, or not TB; ideally should also specify whether the TB was bacteriologically confirmed or not (in accordance with national guidelines)	Patient register
TB treatment	Categorical	Specify whether TB treatment was started, ideally with TB treatment registration number.	TB register
Date of starting TB treatment	Date		TB register

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Example participant enrollment form - SOS Stoolbox

Explanation: This is an example of an enrollment form to be filled by the clinician at enrollment of the participant. Questions marked with * are considered to be "must have".

Participant identification (Unique identification code, preferably as preprinted sticker)		
Details of enrollment and patient demographics		
1	Name of clinician	
2*	Date of enrollment	__ / __ / ____ dd / mm / yyyy
3	Name of participant ¹	
4	Date of birth If unknown → skip to Q5	__ / __ / ____ After filling → skip to Q6 dd / mm / yyyy
5*	Age Fill age in months if <1 year	____ Years __ Months
6*	Sex	<input type="radio"/> Male <input type="radio"/> Female
Reason(s) for being regarded a presumptive TB patient at initial assessment		
7a	Cough of > 2 weeks	<input type="radio"/> Yes <input type="radio"/> No
7b	Poor weight gain or loss of weight	<input type="radio"/> Yes <input type="radio"/> No
7c	Reduced playfulness	<input type="radio"/> Yes <input type="radio"/> No
7d	Unexplained fever	<input type="radio"/> Yes <input type="radio"/> No
7e	Drenching night sweats	<input type="radio"/> Yes <input type="radio"/> No
7f	Lymph nodes in neck enlarged	<input type="radio"/> Yes <input type="radio"/> No
7g	Contact history with infectious TB patient	<input type="radio"/> Yes <input type="radio"/> No
Health-related conditions		
8*	HIV status	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Unknown
9	Other immunosuppressing diseases?	<input type="radio"/> Yes, specify: _____ _____ <input type="radio"/> No
10	Other relevant disease/medical condition	<input type="radio"/> Yes, specify: _____ _____ <input type="radio"/> No

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¹ While a patient name should not be essential if a unique patient identification code is consistently used, experience learns that it may still be needed to link different forms and solve issues with the patient identification code. Ideally, patient name should not be entered in the database. Paper forms with patient names should be kept in a save location that is only accessible to the research/pilot implementation team, e.g. in a locked cabinet.

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Example participant enrollment form - SOS Stoolbox

Participant identification

(Unique identification code, preferably as preprinted sticker)

Samples collected

11a*	Was a respiratory sample collected?	<input type="radio"/> Yes, spontaneously expectorated sputum <input type="radio"/> Yes, nasogastric aspirate (NGA) <input type="radio"/> Not collected → skip to Q12a	
11b*	Date of respiratory sample collection	__ / __ / ____ dd / mm / yyyy	
12a*	Was a stool sample requested?	<input type="radio"/> Yes <input type="radio"/> No → skip to Q13	
12b*	Date of stool sample collection	__ / __ / ____ dd / mm / yyyy	
13	Were any other diagnostic samples requested? <i>Tick all that apply and fill date for each sample ticked</i> <i>If no other samples were collected → skip to Q14</i>	Sample <input type="checkbox"/> Pleural fluid <input type="checkbox"/> Cerebral spinal fluid (CSF) <input type="checkbox"/> Peritoneal fluid <input type="checkbox"/> Pericardial fluid <input type="checkbox"/> Lymph node aspirate <input type="checkbox"/> Other, specify: _____	Collection date dd / mm / yyyy __ / __ / ____ __ / __ / ____ __ / __ / ____ __ / __ / ____ __ / __ / ____ __ / __ / ____
14	Was chest X-ray requested?	<input type="radio"/> Yes <input type="radio"/> No	

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Example laboratory form – SOS Stoolbox

Explanation: *This is an example of a laboratory form that captures results of diagnostic tests from the laboratory. Questions marked with * are considered as “must have”; (*) as must have if applicable.*

Participant identification

(Unique identification code, preferably as preprinted sticker)

General information

1a	Name of laboratory/clinic	
1b	This form was completed by (name)	
2a	Name of participant	
2b	Date of birth If unknown → skip to Q5	__ / __ / ____ After filling → skip to Q2d dd / mm / yyyy
2c*	Age If age <1year, fill age in months	__ Years __ Months
2d*	Sex	<input type="radio"/> Male <input type="radio"/> Female
Respiratory sample		
3*	Is a respiratory sample available?	<input type="radio"/> Yes <input type="radio"/> No, reason: After filling → skip to Q13 <input type="radio"/> sample lost <input type="radio"/> leaking container <input type="radio"/> other, specify: _____
4(*)	Date sample collected	__ / __ / ____ dd / mm / yyyy
5	Date sample received in the laboratory	__ / __ / ____ dd / mm / yyyy
6	Type of respiratory sample received	<input type="radio"/> NGA <input type="radio"/> Sputum
7	Appearance	<input type="radio"/> Watery/salivary <input type="radio"/> Mucoid <input type="radio"/> Purulent <input type="radio"/> Bloody
8	Approximate volume sample	__ mL

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Example laboratory form – SOS Stoolbox

Participant identification			
(Unique identification code, preferably as preprinted sticker)			
Respiratory sample, continued			
9 ^(*)	Date Xpert test conducted	__ / __ / ____ dd / mm / yyyy	
10a ^(*)	Xpert MTB/RIF test result	MTB <input type="radio"/> not detected <input type="radio"/> detected, trace <input type="radio"/> detected, very low <input type="radio"/> detected, low <input type="radio"/> detected, medium <input type="radio"/> detected, high <input type="radio"/> invalid <input type="radio"/> error, code ____ <input type="radio"/> no result, specify: _____	RIF resistance <input type="radio"/> not detected <input type="radio"/> detected <input type="radio"/> indeterminate
10b	Sample Processing Control (SPC) Cycle threshold (Ct) value	____ <input type="checkbox"/> no SPC-Ct value (no test result ²)	
11 ^(*)	If no test result² was obtained, was the test repeated? <i>If test result was MTB (not) detected → skip to Q13</i>	<input type="radio"/> Yes, date: __ / __ / ____ dd / mm / yyyy <input type="radio"/> No, reason: <i>After filling → skip to Q13</i> <input type="radio"/> sample lost <input type="radio"/> not enough sample left <input type="radio"/> other, specify: _____	
12a ^(*)	Repeat Xpert MTB/RIF test result	MTB <input type="radio"/> not detected <input type="radio"/> detected, trace <input type="radio"/> detected, very low <input type="radio"/> detected, low <input type="radio"/> detected, medium <input type="radio"/> detected, high <input type="radio"/> invalid <input type="radio"/> error, code: ____ <input type="radio"/> no result, specify: _____	RIF resistance <input type="radio"/> not detected <input type="radio"/> detected <input type="radio"/> indeterminate
12b	SPC-Ct value	____ <input type="checkbox"/> no SPC-Ct value (no test result ²)	

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² I.e., test result was invalid, error, or there was no test result

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Example laboratory form – SOS Stoolbox

Participant identification

(Unique identification code, preferably as
preprinted sticker)

Stool sample

13*	Is a stool sample available?	<input type="radio"/> Yes <input type="radio"/> No, reason: <i>After filling → skip to Q23</i> <input type="radio"/> sample lost <input type="radio"/> leaking container <input type="radio"/> other, specify: _____	
14^(*)	Date of sample collection	__ / __ / ____ dd / mm / yyyy	
15	Time of sample collection	__ / __ hh / mm	
16	Date sample received in laboratory	__ / __ / ____ dd / mm / yyyy	
17	Time sample received in laboratory	__ / __ hh / mm	
18^(*)	Appearance	<input type="radio"/> Formed (solid) <input type="radio"/> Unformed (soft) <input type="radio"/> Taking the shape of the container (liquid)	
19^(*)	Date Xpert test conducted	__ / __ / ____ dd / mm / yyyy	
20a^(*)	Xpert MTB/RIF test result	MTB <input type="radio"/> not detected <input type="radio"/> detected, trace <input type="radio"/> detected, very low <input type="radio"/> detected, low <input type="radio"/> detected, medium <input type="radio"/> detected, high <input type="radio"/> invalid <input type="radio"/> error, code: ____ <input type="radio"/> no result, specify: _____	RIF resistance <input type="radio"/> not detected <input type="radio"/> detected <input type="radio"/> indeterminate
20b	SPC-Ct value	____ <input type="checkbox"/> no SPC-Ct value (no test)	
21^(*)	If no test result² was obtained, was the test repeated? <i>If test result was MTB (not) detected → skip to Q23</i>	<input type="radio"/> Yes, date: __ / __ / ____ dd / mm / yyyy <input type="radio"/> No, reason: <i>After filling → skip to Q23</i> <input type="radio"/> sample lost <input type="radio"/> not enough sample left <input type="radio"/> other, specify: _____	

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Example laboratory form – SOS Stoolbox

Participant identification

(Unique identification code, preferably as
preprinted sticker)

Stool sample, continued

22a^(*)	Repeat Xpert MTB/RIF test result	MTB <input type="radio"/> not detected <input type="radio"/> detected, trace <input type="radio"/> detected, very low <input type="radio"/> detected, low <input type="radio"/> detected, medium <input type="radio"/> detected, high <input type="radio"/> invalid <input type="radio"/> error, code: _ _ _ <input type="radio"/> no result, specify: _____	RIF resistance <input type="radio"/> not detected <input type="radio"/> detected <input type="radio"/> indeterminate
22b	SPC-Ct value	_ _ _ <input type="checkbox"/> no SPC-Ct value (no test result ²)	

Other diagnostic tests done for this participant

23	Sample type	Test(s) conducted (circle appropriate):	Test result
23a	Sputum	<input type="radio"/> Culture MGIT/LJ <input type="radio"/> Smear microscopy direct ZN/FM <input type="radio"/> MODS <input type="radio"/> Other: _____	<input type="radio"/> positive <input type="radio"/> negative <input type="radio"/> no result <input type="radio"/> positive <input type="radio"/> negative <input type="radio"/> no result <input type="radio"/> positive <input type="radio"/> negative <input type="radio"/> no result <input type="radio"/> positive <input type="radio"/> negative <input type="radio"/> no result
23b	Urine	<input type="radio"/> Urine LAM <input type="radio"/> Culture MGIT/LJ <input type="radio"/> Other: _____	<input type="radio"/> positive <input type="radio"/> negative <input type="radio"/> no result <input type="radio"/> positive <input type="radio"/> negative <input type="radio"/> no result <input type="radio"/> positive <input type="radio"/> negative <input type="radio"/> no result
23c	Lymph node aspirate	<input type="radio"/> Culture MGIT/LJ <input type="radio"/> Other: _____	<input type="radio"/> positive <input type="radio"/> negative <input type="radio"/> no result <input type="radio"/> positive <input type="radio"/> negative <input type="radio"/> no result
23d	Cerebral spinal fluid (CSF)	<input type="radio"/> Culture MGIT/LJ <input type="radio"/> Other: _____	<input type="radio"/> positive <input type="radio"/> negative <input type="radio"/> no result <input type="radio"/> positive <input type="radio"/> negative <input type="radio"/> no result
23f	Bronchoalveolar lavage (BAL)	<input type="radio"/> Culture MGIT/LJ <input type="radio"/> Other: _____	<input type="radio"/> positive <input type="radio"/> negative <input type="radio"/> no result <input type="radio"/> positive <input type="radio"/> negative <input type="radio"/> no result
23g	Other, specify: _____	Specify: _____	<input type="radio"/> positive <input type="radio"/> negative <input type="radio"/> no result
24	Any remarks on any of the laboratory procedures above _____ _____ _____		

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Example diagnosis form – SOS toolbox

Explanation: This is an example of a form that captures the final diagnosis of the participant. Questions marked with * are considered as “must have”.

Participant identification			
(Unique identification code, preferably as preprinted sticker)			
General information			
1	Name of clinician		
2	Name of participant		
3	Date of birth <i>If unknown → skip to Q4</i>	__ / __ / ____ <i>After filling → skip to Q5</i> <i>dd / mm / yyyy</i>	
4*	Age <i>If age <1year, fill age in months</i>	____ Years __ Months	
5*	Sex	<input type="radio"/> Male <input type="radio"/> Female	
Final diagnosis			
6*	Was a TB diagnosis made?	<input type="radio"/> Yes <input type="radio"/> No → End of questionnaire	
7*	How was the TB diagnosis made?	<input type="radio"/> Based on clinical signs and symptoms only → skip to Q9 <input type="radio"/> Based a combination of signs, symptoms and bacteriology <input type="radio"/> Other, specify: _____	
8	On what test result(s) was the bacteriological diagnosis based? <i>Tick all that apply and fill date for each test ticked</i> <i>After filling, → skip to Q10</i>	<u>Positive</u> test result: <input type="checkbox"/> Xpert on sputum/NGA: <input type="checkbox"/> Xpert on stool: <input type="checkbox"/> Other test(s), specify: 1. _____ 2. _____	Date result received by clinician: <i>dd / mm / yyyy</i> __ / __ / ____ __ / __ / ____ __ / __ / ____ __ / __ / ____
9	In case TB was diagnosed clinically, based on what information was the diagnosis made? <i>Tick all that apply</i>	<input type="checkbox"/> Chronic cough <input type="checkbox"/> Chest X-ray abnormal, suggestive of TB <input type="checkbox"/> Contact history with infectious TB patient <input type="checkbox"/> Weight loss or failure to gain weight <input type="checkbox"/> Fever <input type="checkbox"/> Drenching night sweats <input type="checkbox"/> Other, specify: _____	
TB treatment			
10*	Was TB treatment started?	<input type="radio"/> Yes, treatment start date: __ / __ / ____ <i>dd / mm / yyyy</i> <input type="radio"/> Patient referred for treatment to: <i>(Name health facility):</i> _____ <input type="radio"/> Not started, because TB was not diagnosed <input type="radio"/> Not started, reason (specify): _____	