



September 4, 2019

Dear OSPHL Tuberculosis Testing Clients,

Over the past several months, Oregon State Public Health Laboratory (OSPHL) staff have engaged in a project to improve the clarity of tuberculosis testing result reports delivered to your facilities. Beginning October 1, 2019, you will begin to see reports delivered with more distinct results.

What is changing?

The changes detailed apply to reports delivered via Copia, fax, and electronic interfaces. Pertinent changes you will notice on your reports are as follows.

- Results will clearly distinguish between multiple tests performed on the instrument, rather than resulting two results within the same test.
- Results will clearly describe whether the result is from liquid versus solid media.
- Test names have been edited to clarify for which PCR results are provided (e.g., Real-time PCR on an isolate vs. GeneXpert on processed sputum).
- Results will more clearly distinguish between preliminary and final susceptibility testing results.

Examples of the changes to the reports are provided at the end of this message. We encourage you to print each report and review them side-by-side for differences between them.

What is not changing?

There is no change to ordering tuberculosis testing from the OSPHL. Reports will continue to be delivered using existing methods.

We hope this message provides you with sufficient information to understand the new and improved reports from the OSPHL. Please do not hesitate to contact us with questions.

Questions may be directed to Caitlin Miranda, Tuberculosis Testing Lead, at 503-693-4100 or caitlin.miranda@dhsosha.state.or.us or Sarah Humphrey, Client Services Coordinator, at 503-693-4124 or sarah.m.humphrey@dhsosha.state.or.us.

Sincerely,

John Fontana, PhD, (HCLD) ABB
Director, OSPHL

Marisa Frieder, PhD
Manager, General Microbiology

Attachments:

1. Current Result Report – in use – annotated
2. Future Result Report – includes revisions – annotated
3. Current and Future Susceptibility Pending Examples

Patient name:	EXAMPLE, OLD ONE (M)	Marion County - Paper Order
Chart Number:		3180 Center St NE
Date of Birth:	10/8/1969	Salem, OR 97301 U.S.A.
County of Residence:	Marion	(503) 588-5342
Date Collected:	2/22/2019	
Date Received:	2/25/2019	Clinician: Cirino, Christopher M., DO
PHL ID Number:	1901555568	Report Date: 4/4/2019

AFB Smear/Culture

Report Currently In Use

Final Report

Specimen Source
Sputum

AFB SMEAR
[2/25/2019 3:02 PM SCT]
Positive 4+

GeneXpert
[2/25/2019 3:02 PM SCT]
MTB DETECTED; Rif Resistance NOT DETECTED

GeneXpert results are combined.

GeneXpert Reference Range
GeneXpert Normal Result = MTB Not Detected

GeneXpert Comment
[2/25/2019 3:02 PM SCT]
The Cepheid GeneXpert MTB/RIF assay is an FDA-cleared nucleic acid amplified test (NAAT) for the detection of Mycobacterium tuberculosis and associated rifampin resistance. This test is approved for sputum samples only from patients who have not undergone greater than 72 hours of anti-tuberculosis therapy. The MTB/RIF assay does not distinguish between viable and non-viable organisms and should not be used as a measure of treatment efficacy. Evidence of M. tuberculosis infection and potential antibiotic resistance is based on the NAAT results and should be corroborated with further testing and clinical evaluation.

AFB Smear Reference Range
AFB Smear Normal Result = AFB not seen

CULTURE COLONY COUNT
[3/5/2019 4:14 PM CM] AFB isolated from MGIT
[3/11/2019 3:46 PM JTT] AFB isolated 4+ colonies

MGIT results are included within the Colony Count test. Solid and liquid media results are not clearly defined.

AFB PCR Result
[3/6/2019 3:46 PM CM]
Mycobacterium tuberculosis complex DNA by real-time PCR: DETECTED
Mycobacterium avium complex DNA by real-time PCR: Not Detected

Result does not clearly define which testing method was used.

AFB PCR Reference Range
AFB PCR Normal Result = Not Detected

AFB Smear/Culture (cont'd)

AFB PCR Comment

[3/6/2019 3:46 PM CM] This test was developed and its performance characteristics determined by the Oregon State Public Health Lab. It has not been cleared by the FDA. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.
[3/6/2019 4:13 PM JTT] Susceptibility testing to follow

MGIT PZA SUSCEPTIBILITY

[3/22/2019 9:49 AM JTT]

PZA 100 ug/ml Susceptible

INDIRECT SUSCEPTIBILITY

[3/21/2019 9:18 AM JTT] No growth observed to date; final sus

[3/28/2019 8:56 AM JTT] No evidence of antibiotic resistance

[4/4/2019 8:12 AM SCT]

Isoniazid 0.2 ug/ml	Susceptible	0.13% Resistance
Isoniazid 1.0 ug/ml	Susceptible	
Rifampin 1.0 ug/ml	Susceptible	
Ethambutol 5.0 ug/ml	Susceptible	
Ethambutol 10.0 ug/ml	Susceptible	
Ofloxacin 2.0 ug/ml	Susceptible	

It can sometimes be unclear what results are final or preliminary.

Patient name:	EXAMPLE, NEW ONE (F)	Providence Hood River Hospital
Chart Number:		PO Box 149
Date of Birth:	2/16/1970	Attn: Lab
County of Residence:	Hood River	Hood River, OR 97031
Date Collected:	8/15/2019	(541) 386-3911
Date Received:	8/15/2019	Clinician: Deleon, Clarabel, PA
PHL ID Number:	19081500013	Report Date: 8/15/2019

AFB Smear/Culture

Future Report, Begins 10/1/2019

Final Report

Specimen Source
Sputum

Each test on the report is capitalized. Result follows.

AFB SMEAR
[8/15/2019 3:30 PM MSY] Positive 4+

AFB Smear Reference Range
AFB Smear Normal Result = AFB not seen

GENEXPERT MYCOBACTERIUM TUBERCULOSIS
[8/15/2019 3:31 PM MSY] DETECTED

GeneXpert results are split into separate tests.

GENEXPERT RIF RESISTANCE
[8/15/2019 3:32 PM MSY] Not Detected

GeneXpert Reference Range
GeneXpert Normal Result = MTB Not Detected

GeneXpert Comment
[8/15/2019 3:32 PM MSY] The Cepheid GeneXpert MTB/RIF assay is an FDA-cleared nucleic acid amplified test (NAAT) for the detection of Mycobacterium tuberculosis and associated rifampin resistance. This test is approved for sputum samples only from patients who have not undergone greater than 72 hours of anti-tuberculosis therapy. The MTB/RIF assay does not distinguish between viable and non-viable organisms and should not be used as a measure of treatment efficacy. Evidence of M. tuberculosis infection and potential antibiotic resistance is based on the NAAT results and should be corroborated with further testing and clinical evaluation.

AFB CULTURE BY SOLID MEDIA
[8/15/2019 3:32 PM MSY] Presumptive Mycobacterium tu

Results for testing by MGIT and on solid media are clearly distinguished

AFB CULTURE BY MGIT
[8/15/2019 3:34 PM MSY] AFB isolated

MYCOBACTERIUM TUBERCULOSIS COMPLEX DNA RT-PCR
[8/15/2019 3:33 PM MSY] DETECTED

Results clearly show this result is for the DNA RT-PCR test.

MYCOBACTERIUM AVIUM COMPLEX DNA RT-PCR
[8/15/2019 3:33 PM MSY] Not Detected

Mycobacterium PCR Reference Range

Future Report, Begins 10/1/2019

AFB Smear/Culture (cont'd)

Mycobacterium PCR Normal Result = Not Detected

Mycobacterium PCR Comment

[8/15/2019 3:33 PM MSY] This test was developed and its performance characteristics determined by the Oregon State Public Health Lab. It has not been cleared by the FDA. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

MGIT SUSCEPTIBILITY PZA 100ug/ml

[8/15/2019 3:35 PM MSY] Susceptible

FINAL INDIRECT SUSCEPTIBILITY ISONIAZID 0.2 ug/ml

[8/15/2019 3:39 PM MSY] Susceptible

FINAL INDIRECT SUSCEPTIBILITY ISONIAZID 1.0 ug/ml

[8/15/2019 3:40 PM MSY] Susceptible

FINAL INDIRECT SUSCEPTIBILITY RIFAMPIN 1.0 ug/ml

[8/15/2019 3:40 PM MSY] Susceptible

FINAL INDIRECT SUSCEPTIBILITY ETHAMBUTOL 5.0 ug/ml

[8/15/2019 3:40 PM MSY] Susceptible

FINAL INDIRECT SUSCEPTIBILITY ETHAMBUTOL 10.0 ug/ml

[8/15/2019 3:40 PM MSY] Susceptible

FINAL INDIRECT SUSCEPTIBILITY OFLOXACIN 2.0 ug/ml

[8/15/2019 3:40 PM MSY] Susceptible

While this example includes only Final results, if a result is preliminary it will be clearly stated here as well.

Current and Future Susceptibility Pending Examples

Current/Old

[3/6/2019 4:13 PM JTT] Susceptibility testing to follow

Future

Susceptibility Comment

[8/15/2019 3:35 PM MSY] Indirect Susceptibility testing to follow