

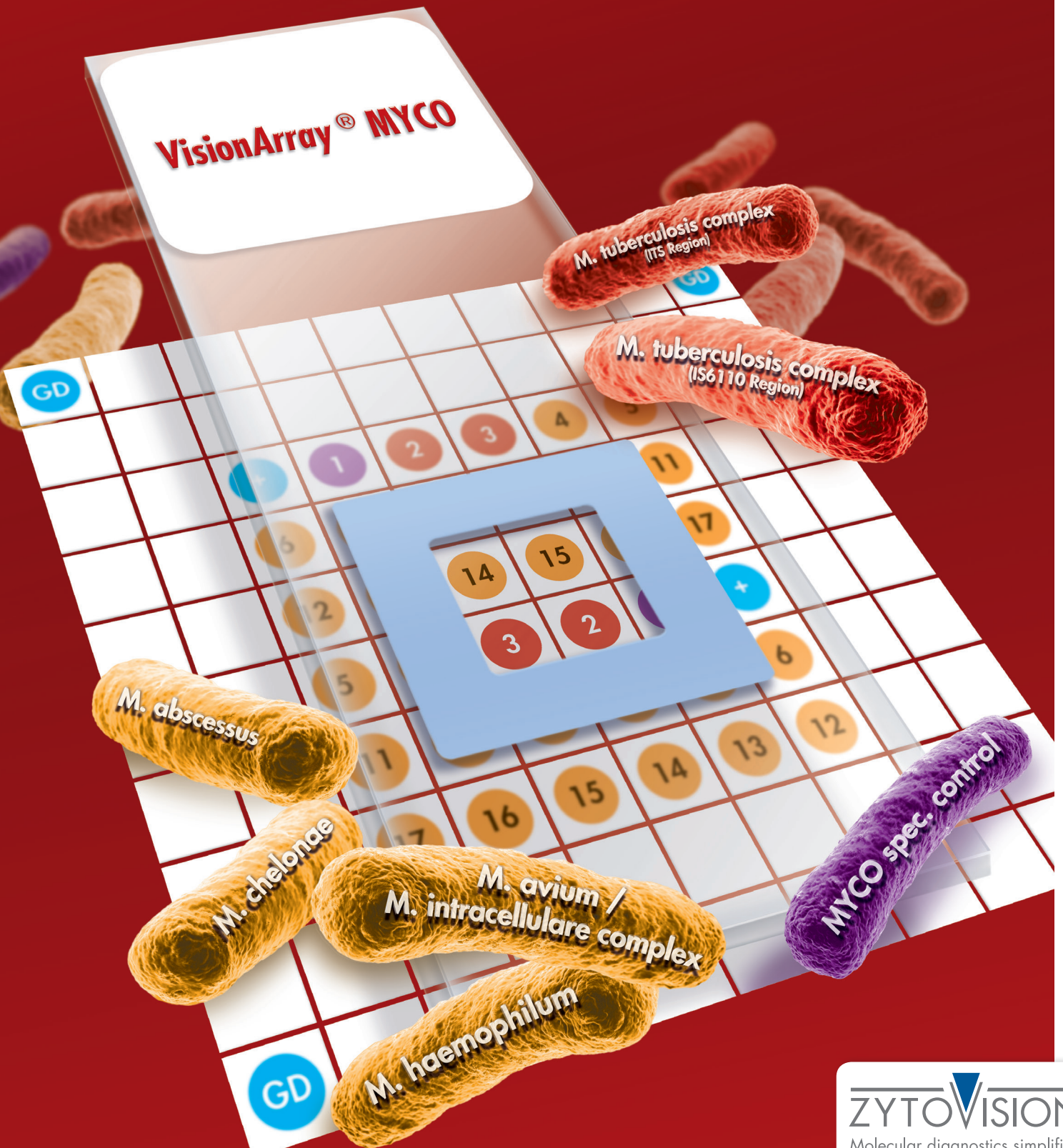


VisionArray®

Arrays for DNA analysis

Qualitative Detection & Identification of

- **M. tuberculosis complex (MTC)**
- **Nontuberculous Mycobacteria (NTM)**



VisionArray® MYCO Chip - Fast and Reliable Genotyping

The genus *Mycobacterium* comprises more than 140 species, which, for the purpose of diagnosis and treatment, has been grouped into three categories: *M. tuberculosis* complex (MTC), *M. leprae*, and nontuberculous mycobacteria (NTM). In the WHO European region, approximately 300,000 tuberculosis cases have been notified in 2016. The majority of the *Mycobacterium* species belongs to the NTM group and many of these bacteria cause life-threatening infections in humans. Pulmonary manifestations account for 80-90% of all NTM-associated diseases and the differentiation between tuberculosis pathogens and NTM is essential for diagnosis and treatment. No standard treatment of NTMs exists. Therefore, a clear distinction between the present species is of highest importance.

The VisionArray® MYCO Chip 1.0 is intended to be used with a VisionArray® Analysis Package for the qualitative detection and identification of PCR amplicates of the genera *Mycobacterium*, *Mycobacteriodes*, *Mycolicibacillus*, *Mycolicibacter*, and *Mycolicibacterium* as well as several additional clinically relevant mycobacterial species that have been produced with the help of the VisionArray® MYCO Primer Kit 1.0 or the VisionArray® MYCO PreCise Master Mix.

M. tuberculosis complex (MTC)

2 **M. tuberculosis complex (ITS Region)**

3 **M. tuberculosis complex (IS6110 Region)**

- *M. tuberculosis*
- *M. bovis*
- *M. africanum*
- *M. caprae*
- *M. microti*
- *M. pinnipedii*

Nontuberculous Mycobacteria (NTM)

4 **M. abscessus**

8 **M. genavense**

5 **M. avium /
M. intracellulare complex**

9 **M. haemophilum**

- *M. avium*
- *M. chimaera*
- *M. arosiense*
- *M. timonense*
- *M. yongonense*
- *M. lepraemurium*
- *M. intracellulare*
- *M. colombiense*
- *M. bouchardurhonense*
- *M. marseillense*
- *M. paraintracellulare*

10 **M. kansasii**

11 **M. malmoense**

12 **M. marinum / M. ulcerans**

13 **M. scrofulaceum /
M. parascrofulaceum**

14 **M. simiae**

15 **M. smegmatis**

6 **M. chelonae**

16 **M. szulgai**

7 **M. fortuitum**

17 **M. xenopi**

GD										GD
		+	1	2	3	4	5			
		6	7	8	9	10	11			
		12	13	14	15	16	17			
		5	4	3	2	1	+			
		11	10	9	8	7	6			
		17	16	15	14	13	12			
GD										

GD **Guide Dot**

+ **Positive Control**

1 **MYCO spec.**

References

- Griffith DE, et al. (2007) *Am J Respir Crit Care Med* 175: 367-416.
- Gupta RS, et al. (2018) *Front Microbiol* 9: 67.
- Oren A & Carrity GM (2019) *Int J Syst Evol Microbiol* 69: 597-9.
- Perez-Martinez I, et al. (2013) *BMC Res Notes* 6: 531.
- Simons S, et al. (2011) *Emerg Infect Dis* 17: 343-9.
- Tortoli E (2009) *Clin Microbiol Infect* 15: 906-10.

1. Sample Collection

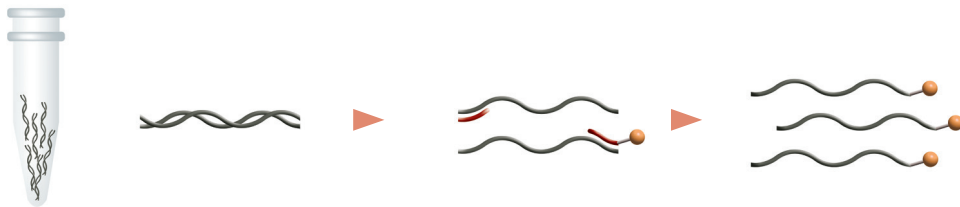
For the detection of MTC and NTMs genotypes with the VisionArray® MYCO system the following raw material can be used for DNA extraction:

- Clinical specimens such as formalin-fixed, paraffin-embedded tissue samples
- Pulmonary smears
- Cultivated samples

DNA extractions should be done following the protocols/ methods established and validated in the respective laboratory.

2. Detection & Differentiation of the most relevant Mycobacteria Species

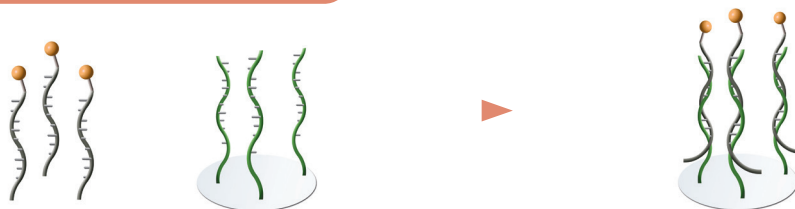
Step 1: Amplification and Labeling by PCR



Biotinylated primers are used to amplify and label different sections of the ITS and, in case of the *M. tuberculosis* complex, IS6110 region of the mycobacterial genome.

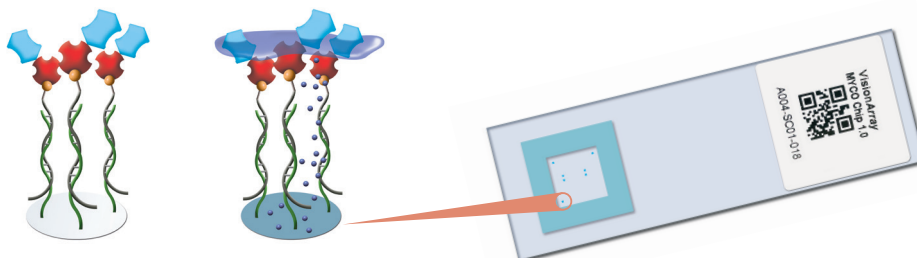
The human HLA-DQA1 gene is also amplified and serves as a PCR positive control and as a genomic control.

Step 2: Hybridization on the Glass Chip



After amplification, the biotinylated sequences hybridize to complementary DNA capture sequences on the glass chip.

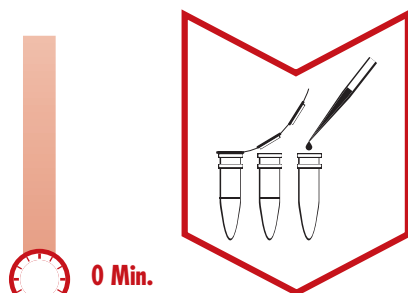
Step 3: Detection and Visualization



Specifically bound and biotinylated sequences are visualized by secondary marking with a streptavidin-peroxidase conjugate and a staining with tetramethylbenzidine. After color development, evaluation is performed using a VisionArray® Analyzer Software.

3. Workflow Schedule

This is a condensed protocol for the VisionArray® method and should not replace the instruction for use!



0 Min.

PCR

- For the PCR the ready-to-use **VisionArray® MYCO PreCise Master Mix** is used
- The **VisionArray® MYCO PreCise Master Mix** contains the components of the **VisionArray® MYCO Primer Kit 1.0**, the **VisionArray® PreCise Taq DNA Polymerase**, and the **VisionArray® Uracil-DNA Glycosylase**
All reagents can be ordered separately
- DNA sample is added to the master mix

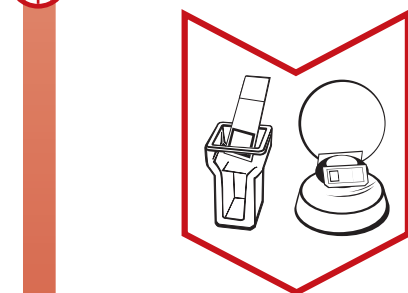


30 Min.

Hybridization

- PCR product and **Hybridization Solution** are mixed well
- Mix is applied onto the **VisionArray® Chip**

Duration: 30 min

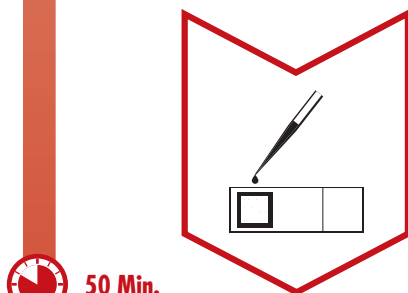


50 Min.

Stringency Wash

- Unbound DNA fragments are removed using **1x Wash Buffer**
- Drying of **VisionArray® Chip** by centrifugation

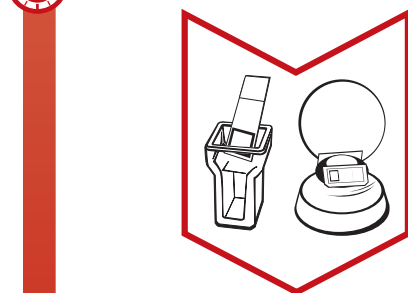
Duration: 2 min



Detection

- Marking of biotinylated sequences using the **Detection Solution**
- Visualization is performed by applying the **Blue Spot Solution**

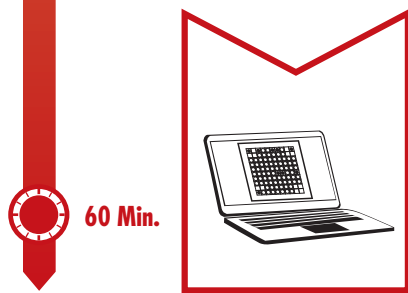
Duration: 17 min



Wash

- Removing of the **Blue Spot Solution** by washing with **1x Wash Buffer**
- Drying of **VisionArray® Chip** by centrifugation

Duration: 2 min



60 Min.

Analysis

- Chips are scanned with the **VisionArray® Scanner 8100** or the **VisionArray® Scanner V600 Photo**
- Automated analysis is performed by using a **VisionArray® Analyzer Software**

Duration: 10 min

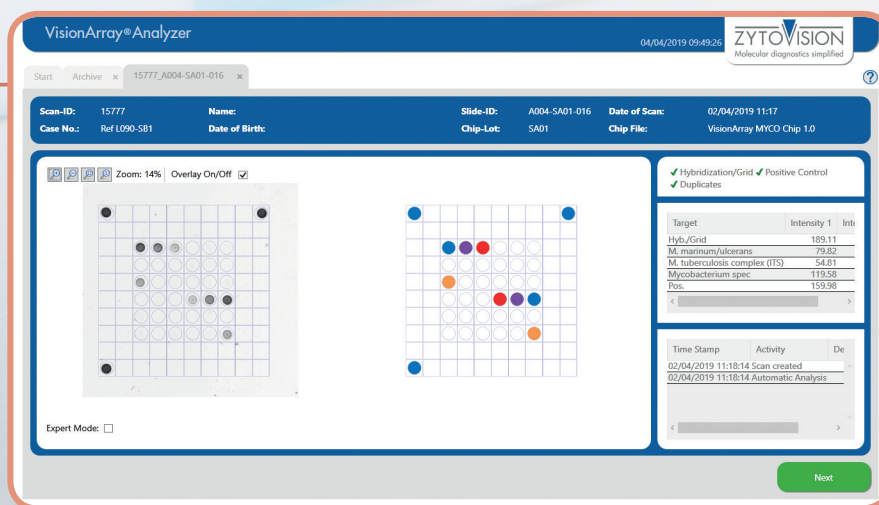
Quick & easy 1 hour protocol · Automated user-friendly evaluation within a few minutes

Mycobacterium Tests in Comparison

Assay	Tuberculosis Test	NTM Test	Automated Evaluation
Cepheid Xpert® MTB/RIF	✓	–	✓
Chipron MYCO Direct 1.7 LCD Assay	✓	✓	✓
Hain Life Science GenoType Mycobacterium CM	✓	✓	–
Vircell SPEED-OLIGO® Tuberculosis	✓	✓	–
Akkoni TruArray® MDR TB Assay	✓	–	✓
Fujirebio INNO-LiPA® Mycobacteria v2	✓	✓	–
VisionArray®	✓	✓	✓

VisionArray® – At a Glance

- Simultaneous genotyping of the most relevant different Mycobacterium species – all certified for *in vitro* diagnostic use
- All capture sequences and positive controls are set up on the VisionArray® Chip as duplicates
- High sensitivity and specificity
- One patient sample - one slide
- Quick & easy 1 hour protocol
- Automated evaluation using a VisionArray® Analyzer Software – simple visualization & quick analysis in just a few minutes



VisionArray® MYCO Chips



Prod. No.	Product	Tests
VA-0003-10	VisionArray MYCO Chip 1.0 CE IVD Incl. 10 pieces	10
VA-0003-50	VisionArray MYCO Chip 1.0 CE IVD Incl. 5x 10 pieces	50

VisionArray® PCR and Detection



Prod. No.	Product	Tests
ES-0008-50	VisionArray MYCO PreCise Master Mix CE IVD Containing MYCO Primer Mix 1.0; dNTP/dUTP Solution; VisionArray PreCise Taq DNA Polymerase; PCR-Buffer; MgCl ₂ ; VisionArray Uracil-DNA Glycosylase	50
VP-0002-50	VisionArray MYCO Primer Kit 1.0 CE IVD Incl. MYCO Primer Mix 1.0; dNTP/dUTP Solution	50
VE-0001-100	VisionArray PreCise Taq DNA Polymerase CE IVD Incl. VisionArray PreCise Taq DNA Polymerase; PreCise Reaction Buffer, 10x; PreCise MgCl ₂ , 25mM	100
VE-0002-100	VisionArray Uracil-DNA Glycosylase CE IVD	100

Prod. No.	Product	Tests
VK-0003-50	VisionArray Detection Kit CE IVD Incl. Hybridization Solution, 1 ml; Detection Solution, 5 ml; Blue Spot Solution, 5 ml; 100x Wash Buffer, 250 ml	50
E-4051-1	Mini Slide Centrifuge	

VisionArray® Analysis Packages



Prod. No.	Product
E-4060-1	VisionArray Analysis Package SingleScan CE IVD Incl. Scanner 8100; Slide Holder SingleScan; Hand Scanner; PC with preinstalled VisionArray Analyzer Software SingleScan; USB-Hub; External Hard Drive; Computer Mouse
E-4070-1	VisionArray Analysis Package MultiScan CE IVD NEW Incl. Scanner V600 Photo; Slide Holder MultiScan; PC with preinstalled VisionArray Analyzer Software MultiScan; USB-Hub; External Hard Drive; Computer Mouse

CE **IVD** only available in certain countries. All other countries research use only! Please contact your local dealer for more information.