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 **HARDY**  
DIAGNOSTICS  
*A Culture of Service™*

**Microscopic Observation Drug Susceptibility Assay**  
A standardized and accelerated liquid culture and direct  
susceptibility testing method for *Mycobacterium tuberculosis*.

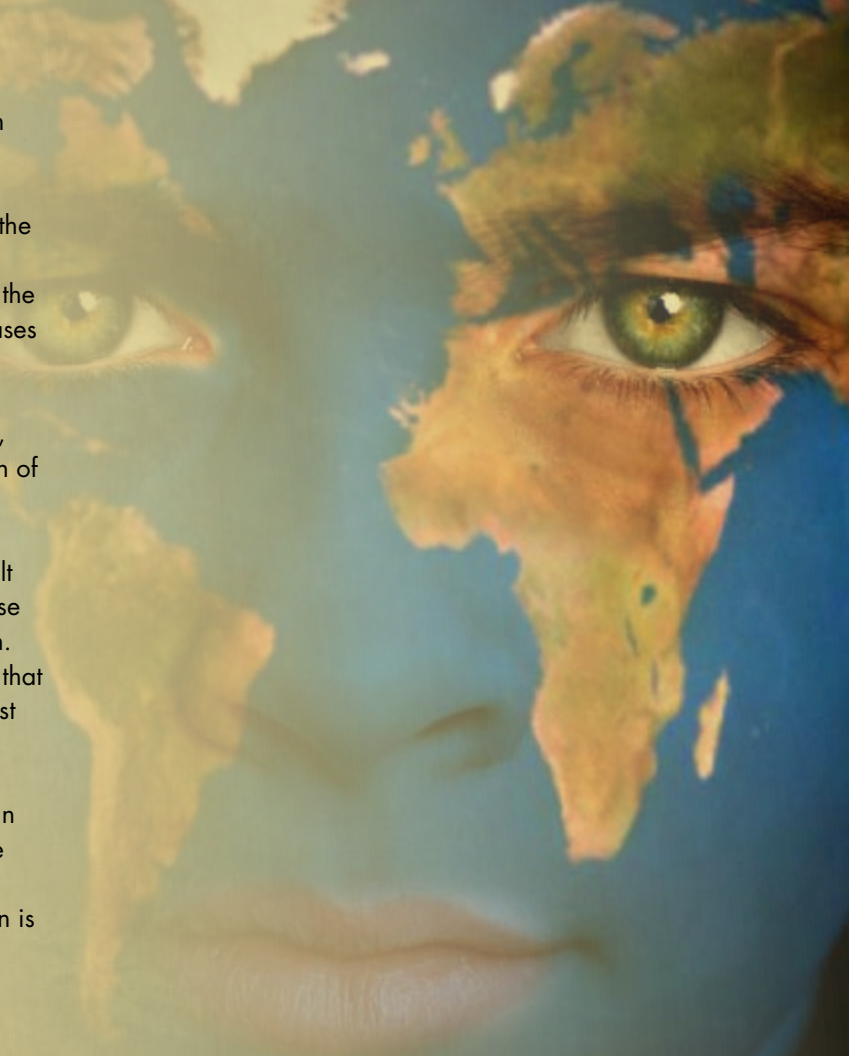


One-third of the world's population is currently infected with *Mycobacterium tuberculosis*. 5-10% of people who are infected with the TB bacillus become ill or infectious at some time during their life. Two million will die every year.



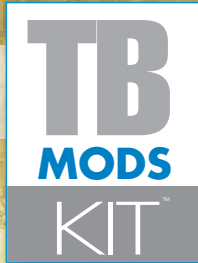
Hardy TB MODS (Microscopic Observation Drug Susceptibility Assay) Kit™ is recommended for use as an accelerated culture and direct drug susceptibility test (DST) method for detection of drug-susceptible, mono-resistant, and multi-drug resistant tuberculosis (MDR-TB).

- Patients co-infected with both HIV and TB are much more likely to develop active TB disease. Almost every country in the world has reported strains of *M. tuberculosis* that are resistant to at least one of the anti-TB drugs.
- In 2008, the World Health Organization reported the prevalence of INH resistance as 10.3% for new cases and 27.7% for previously treated cases.
- In some instances rifampicin mono-resistant strains have been linked to patients who are incarcerated, infected with HIV, or with poor intestinal absorption of TB medications.
- Treatment of rifampicin mono-resistant strains is challenging because alternate drugs can be difficult to administer, are associated with numerous adverse effects, and patient compliance is difficult to obtain.
- In 2008, the World Health Organization reported that strains of XDR *M. tuberculosis* were found in at least 45 countries.
- The majority of diagnosed TB cases occur in developing countries where resources are scarce. In these settings, the diagnosis of tuberculosis may be limited to performing microscopic examination of sputum smears, for which the sensitivity of detection is estimated at only 50%.





Hardy Diagnostics is pleased to present the new



## A solution demanding attention...

**Microscopic Observation Drug Susceptibility Assay**  
A standardized and accelerated liquid culture and direct susceptibility testing method for *Mycobacterium tuberculosis*.

- Simultaneous detection and susceptibility testing to both isoniazid and rifampicin
- Speedy results within 5 to 10 days
- Sensitivity at 97.8%, Specificity at 99.6%
- Standardized ready-to-use color-coded components
- Affordable - no equipment needed other than an inverted microscope
- Identification based on the "cording" phenomenon in liquid culture
- TB MODS Kit is a BSL-2 Kit (Biological Safety Level - 2), not BSL-3
- TB MODS may be used as a follow-up test to PCR. Positive PCR tests for rifampin resistance must be followed up with a culture susceptibility test for isoniazid.



- Kit contains all necessary components. No need to source from multiple vendors.
- Performs identification and susceptibility testing simultaneously and within the same procedure.
- Detects resistance to both isoniazid and rifampicin; the two most commonly used drugs for therapy.
- Uses liquid culture for accelerated *M. tuberculosis* growth.



TB MODS Kit - a complete, simplified, and standardized system.

- Standardized, ready-to-use kit format complete with 24-well trays.
- Special color coding and orientation card for easy use.
- All vials and reagents are color-coded to simplify and error-proof the procedure.



MODS Sealing Lid for safety

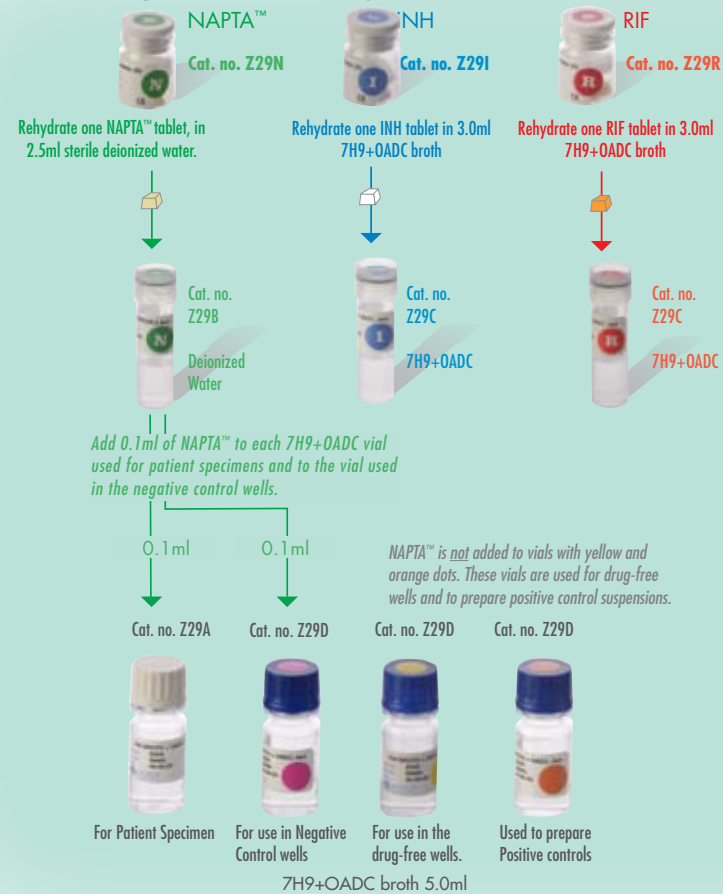
- Unique protective flexible silicone sealing lid for increased safety.
- Tray remains permanently sealed throughout the entire incubation and examination procedure.
- Safety lid can be easily pierced with a needle/syringe if sub-culturing or rapid speciation is necessary.



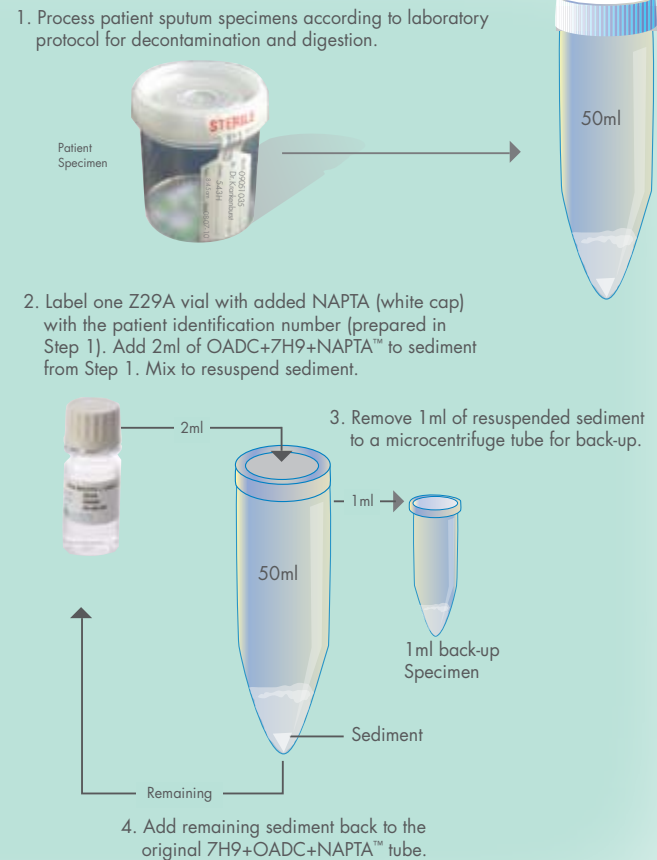
MODS Antibiotic Tablets

- Ready-to-use antibiotics available in an easy-to-dissolve tablet.
- No measuring, weighing, or mixing needed.
- Detects susceptible, mono-resistant, and multi-drug resistant (MDR) TB usually within a 5 to 10 day incubation period.
- Utilizes the TB cording phenomenon for identification, which is easily viewed with an inverted microscope.
- Can be used to monitor patients on therapy; detects only living organisms.

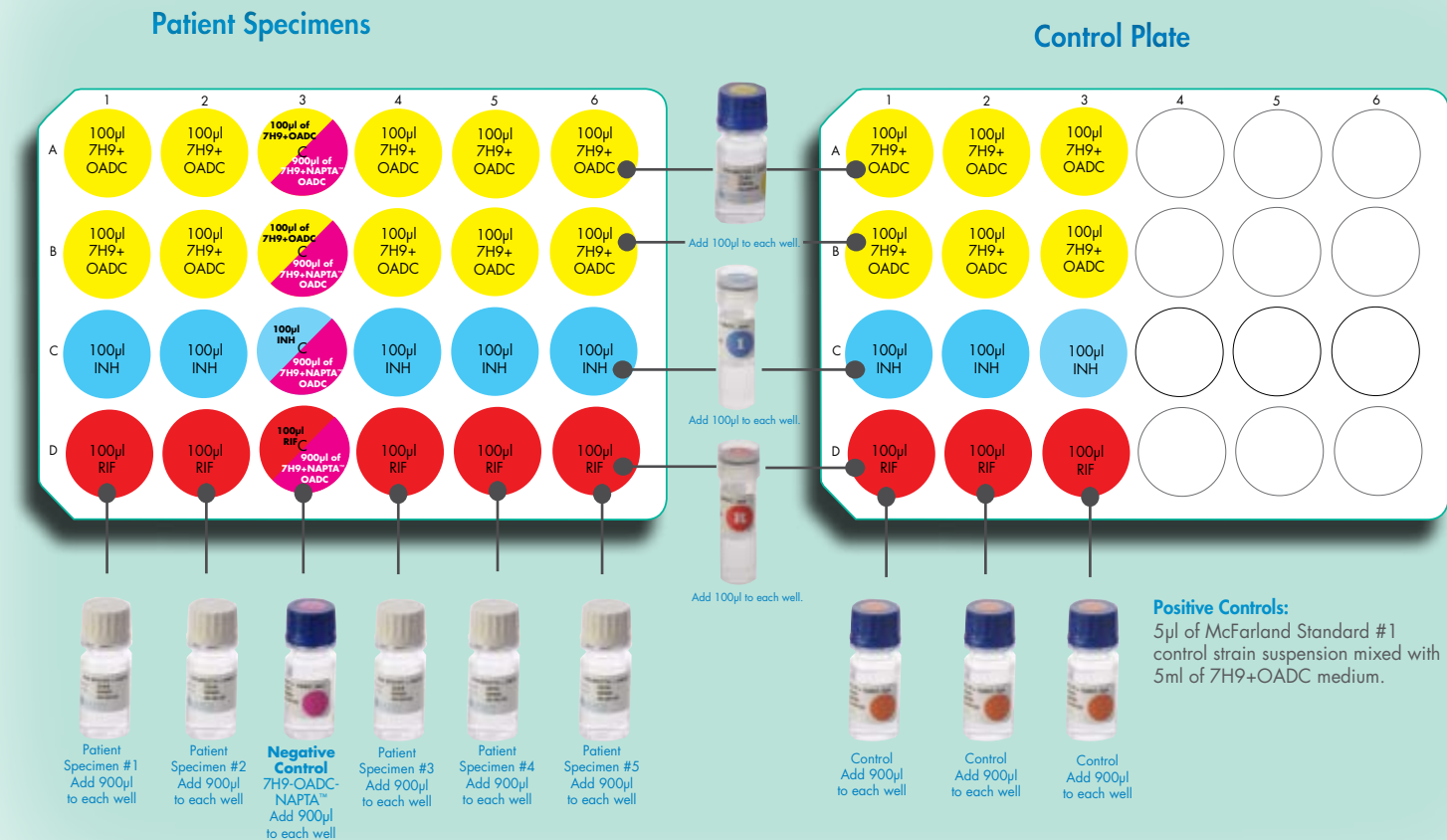
## A. Preparation of Reagents



## B. Processing of Specimens



## C. Inoculation of Trays



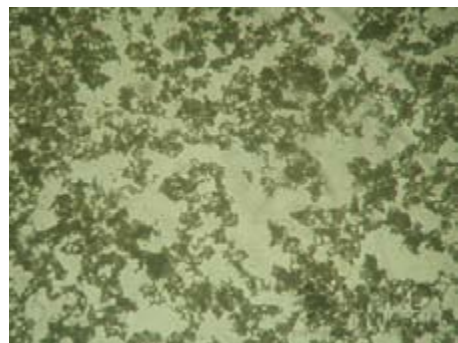




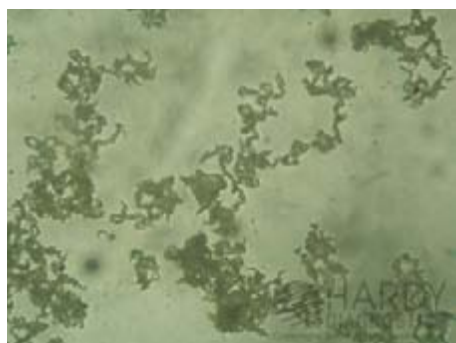
*Mycobacterium tuberculosis* (clinical isolate) growth visible at 7 days at 100x



Inverted Microscope



*Mycobacterium tuberculosis* (clinical isolate) growth with cording visible at 21 days at 40x.



*Mycobacterium tuberculosis* growth with cording visible at 23 days at 40x.

Photos courtesy of the MODS TB Group, Universidad Peruana Cayetano Heredia, Lima, Peru.



Cat. no. TB100	TB MODS Kit™	100 tests/kit
Each kit contains:		
	Z29A Middlebrook 7H9 Broth + OADC, 5ml with white cap	100 vials
	Z29B Deionized Water, 2.5ml (green dot)	5 vials
	Z29C Middlebrook 7H9 Broth + OADC, 3ml (5 red dot, 5 blue dot)	10 vials
	Z29D Middlebrook 7H9 Broth + OADC, 5ml with blue cap	40 vials
	Yellow dot on lid and vial	10 vials
	Pink dot on lid and vial	15 vials
	Orange dot on lid and vial	15 vials
	Z29I Isoniazid Tablets, 5 per vial (blue dot)	1 vial
	Z29R Rifampicin Tablets, 5 per vial (red dot)	1 vial
	Z29N NAPTA™ Tablets, 5 per vial (green dot)	1 vial
	Z29E Silicone Safety Lid (autoclaved)	25 lids
	P52000 Tissue Culture Plate, 24-well	25 trays
	R55800 Orientation Card	1 card

Cat. no. TB50	TB MODS Kit™	50 tests/kit
Each kit contains:		
	Z29A Middlebrook 7H9 Broth + OADC, 5ml with white cap	50 vials
	Z29B Deionized Water, 2.5ml (green dot)	5 vials
	Z29C Middlebrook 7H9 Broth + OADC, 3ml (5 red dot, 5 blue dot)	10 vials
	Z29D Middlebrook 7H9 Broth + OADC, 5ml with blue cap	30 vials
	Yellow dot on lid and vial	5 vials
	Pink dot on lid and vial	10 vials
	Orange dot on lid and vial	15 vials
	Z29I Isoniazid Tablets, 5 per vial (blue dot)	1 vial
	Z29R Rifampicin Tablets, 5 per vial (red dot)	1 vial
	Z29N NAPTA™ Tablets, 5 per vial (green dot)	1 vial
	Z29E Silicone Safety Lid (autoclaved)	15 lids
	P52000 Tissue Culture Plate, 24-well	15 trays
	R55800 Orientation Card	1 card

TB MODS Kit is currently not for sale within the United States.



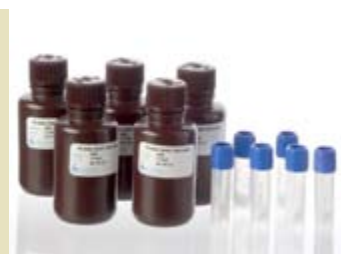
# Available Accessories



N95 rated particulate respirator mask, one size fits all, 210/case (Cat. no. USP10206).



Disposable 1ml serological pipet, UniPlast™, sterile, standard tip, polystyrene, yellow striped, individually wrapped, 500/case, (Cat. no. 1700).



TB DeCon Red™ Kit (Cat. no. Z30). Used for the digestion and decontamination of sputum specimens. Visual color change when neutralization has occurred.



Clockwise from left: graduated 50ml centrifuge tube (Cat. no. 6289), Water with Tween® 80 (Cat. no. V03), TB Diluting Fluid (Cat. no. R54), McFarland Latex Standard 1 (Cat. no. ML1), SpeedStreaks™ disposable 10ul loop (Cat. no. HS10F), nylon tipped flocked swab (Cat. no. FS1HD), graduated 1ml disposable transfer pipet (Cat. no. 2121S), 1.5ml microtube (Cat. no. 111720).



Graduated disposable specimen cup, SureTight, sterile, stackable, 90ml volume, 400 per case, (4 bags of 100/case), tamper proof sterile indicator tab, polypropylene cup with green polyethylene screw cap (Cat. no. 243810)



- Pipet tips, 1-200µl, Universal, Filter, Sterile, graduated, 96/rack, 10 racks/case (Cat. no. 153820).
- 100-1000µl, Universal, Filter, Sterile, 100/rack, 10 racks/case (Cat. no. 153830).



Phosphate Buffer, pH 6.8, 1 L, narrow mouth polypropylene bottle, 10/pack (Cat. no. U192).



MODS test tube rack (Cat. no. 456703) with Middlebrook 7H9 Broth + OADC vials (Cat. no. Z29D).



## Inverted Microscope

For use with the TB MODS KIT™

The VanGuard inverted microscope is recommended for use with the MODS procedure. This trinocular brightfield microscope uses a 30W light source and

features Infinity Corrected Optics. It comes with 4x and 10x fluorite objectives for 40x and 100x total magnification. Five year warranty.

110 volts, each..... 1491INIMODS  
220 volts, each..... 1491INIMODS220



Middlebrook 7H11 Agar, deep fill, 15x100mm plate, 10/pack (Cat. no. W35).



Pipettors, adjustable volume

- 2-20µl, Cat. no. P394020
- 20-200µl, Cat. no. P3940200
- 100-1000µl, Cat. no. P39401000



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