TB MODS KIT™

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.

Hardy TB MODS (Microscopic Observation Drug Susceptibility Assay) Kit™ is recommended for use as an accelerated culture and direct drug susceptibility test (DST) mehod for detection of drug-susceptible, monoresistant, 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 current prevalence of INH resistance as 10.3% for new cases and 27.7% for previously treated cases.
- In some instances rifampicin monoresistant strains have been linked to patients who are incarcerated, infected with HIV, or with poor intestinal absorption of TB medications.
- Treatment of rifampicin monoresistant 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 low (estimated at only 50% sensitive).

Hardy Diagnostics is pleased to present the new

TB MODS KIT™

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 components*
- *Affordable liquid culture method*

TB MODS KIT™

- Kit contains all necessary components. No need to source from multiple vendors.
- Performs 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 growth.

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

- Formulated in a 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

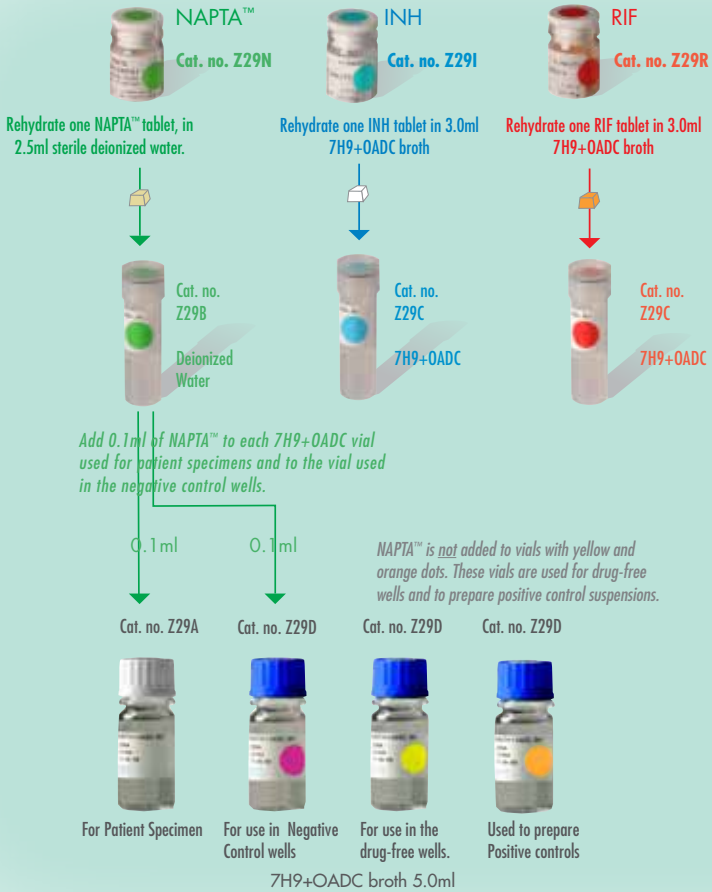
- Unique protective flexible silicone sealing lid for increased safety,
- Tray remains permanently sealed throughout the entire incubation and examination procedure,
- Safety lid can be easily pierced with a needle/syringe if sub-culturing or rapid speciation is necessary.

MODS Antibiotic Tablets

- Ready-to-use antibiotics available in an easy-to-dissolve tablet;
- No measuring, weighing, or mixing needed.

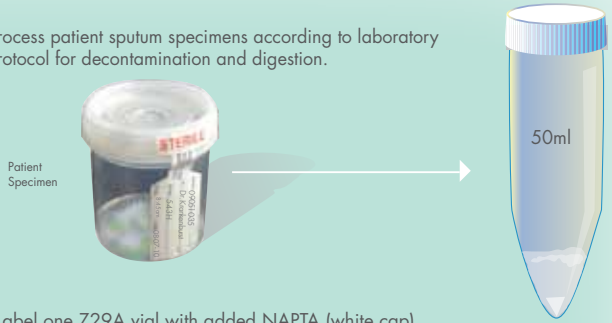
- Detects susceptible, mono-resistant, and multi-drug resistant (MDR) TB usually within a 5 to 10 day incubation period.
- Utilizes the TB cording phenomenon for identification, which is easily viewed with an inverted microscope.
- Can be used to monitor patients on therapy. Detects only living organisms.

A. Preparation of Reagents



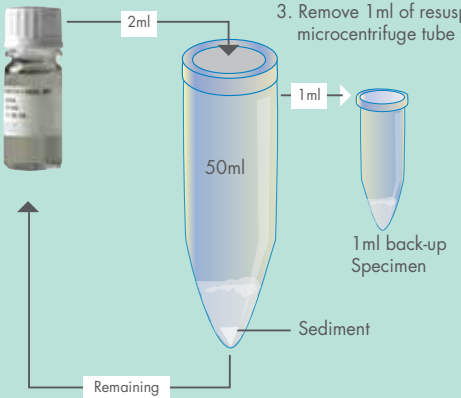
B. Processing of Specimens

1. Process patient sputum specimens according to laboratory protocol for decontamination and digestion.



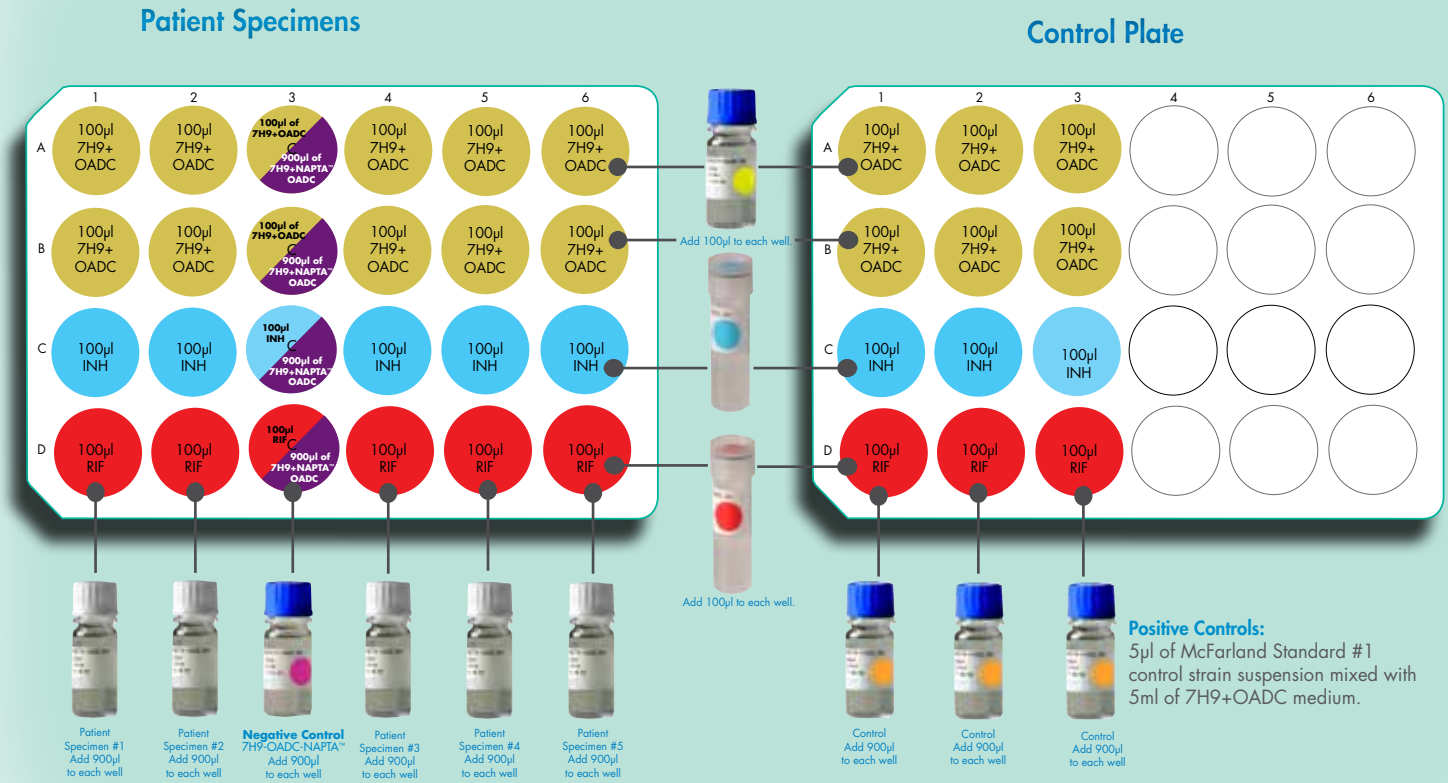
2. Label one Z29A vial with added NAPTA (white cap) with the patient identification number (prepared in Step 1). Add 2ml of OADC+7H9+NAPTA™ to sediment from Step 1. Mix to resuspend sediment.

3. Remove 1ml of resuspended sediment to a microcentrifuge tube for back-up.



4. Add remaining sediment back to the original 7H9+OADC+NAPTA™ tube.

C. Inoculation of Trays



Positive Controls:
5µl of McFarland Standard #1 control strain suspension mixed with 5ml of 7H9+OADC medium.

TB MODS KIT™

Image 2: *Mycobacterium tuberculosis* (clinical isolate) growth visible at 7 days at 100x

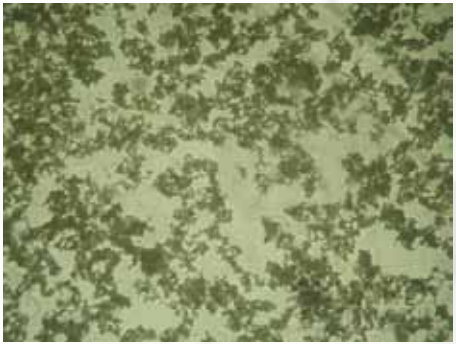


Image 4: *Mycobacterium tuberculosis* (clinical isolate) growth with cording visible at 21 days at 40x.

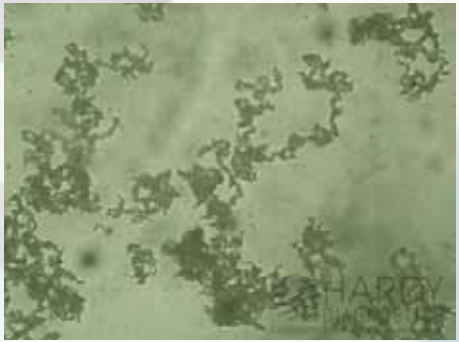


Image 5: *Mycobacterium tuberculosis* growth with cording visible at 23 days at 40x.

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

TB MODS KIT™

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 Middlebroo Z29D Middlebrook 7H9 Broth + OADC, 5ml with blue cap	10 vials 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

Available Accessories

N95 particulate respirator mask (Cat. no. USP10206).

Disposable 1ml serological pipet (Cat. no. P0010S01).

Graduated disposable specimen cup (Cat. no. 243810)

Pipet tips, sterile (1-200µl, Cat. no. 153820; 100-1000µl, Cat. no. 153830).

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

TB DeCon Red™ Kit (Cat. no. Z30). Used for the digestion and decontamination of sputum specimens.

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).

Phosphate Buffer, 1L (Cat. no. U192).

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

Middlebrook 7H11 Agar (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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