

## Importance of Tetracyclines Determination

Antibiotic residues in foods pose a serious threat to public health. Tetracycline is a broad spectrum polyketide antibiotic produced by the *Streptomyces* genus of Actinobacteria. It is used for the treatment and prevention of many bacterial infections. Tetracyclines are widely used in food production, however over use can lead to antibiotic resistance. The monitoring of water sources and food products, such as meat, milk and honey, for antibiotic residues is necessary to ascertain that these compounds are not misused and do not present a danger to human or animal health. The following MRLs for Tetracycline, chlorTetracycline and oxyTetracycline has been recommended by FAO/WHO in cattle, pigs, sheep and poultry: 100 ug/Kg (muscle), 300 ug/Kg (liver), 600 ug/Kg (kidney); 100 ug/L in cattle and sheep milk; 200 ug/Kg in egg (poultry). An MRL of 100 ug/Kg for oxyTetracycline in muscle of giant prawn. Europe has proposed an MRL of 10 ug/Kg for all Tetracyclines in honey.

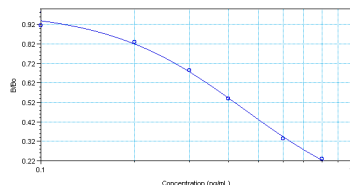
The Abraxis Tetracyclines ELISA allows the determination of 42 samples in duplicate determination. Only a few milliliters of sample are required. The test can be performed in 90 minutes.

## Performance Data

### Test sensitivity:

The limit of detection for Tetracycline in water calculated as  $Xn \pm 3SD$  (n=20) or as 90% B/Bound is equal to <0.10 ng/mL. The concentration of residue necessary to cause 50% inhibition (50% B/B<sub>0</sub>) is approximately 0.40 ng/mL. Determinations closer to the middle of the calibration range of the test yield the most accurate results.

The following is the sensitivity in different matrixes: 4.0 ppb in honey; 4.0 ppb in milk; 8.0 ppb in meat; 4.0 ppb in shrimp; 0.11 ppb in water.



Test reproducibility: Coefficients of variation (CVs) for standards: <10%; CVs for samples: <15%.

Selectivity: This ELISA recognizes Tetracycline and related compounds with varying degrees:

Cross-reactivities:		
Tetracycline		100%
Oxytetracycline		95%
4-epi-tetracycline		95%
Demeclocycline		88%
Rolitetraacycline		82%
Chlortetracycline		81%
4-epi-oxytetracycline		71%
Methacycline		60%
Doxycycline		53%
4-epi-chlortetracycline		29%

Samples: To eliminate matrix effects in meat, milk and honey samples, sample dilution is required. See Preparation of Samples section. For additional extraction procedures for various matrices please contact Abraxis LLC.

General Limited Warranty: Abraxis LLC warrants the products manufactured by the Company against defects and workmanship when used in accordance with the applicable instructions for a period not to extend beyond the product's printed expiration date. **Abraxis makes no other warranty, expressed or implied. There is no warranty of merchantability or fitness for a particular purpose.**

For ordering or technical assistance contact:

India Contact:

**Life Technologies (India) Pvt. Ltd.**

306, Aggarwal City Mall, Road No. 44, Pitampura, Delhi - 110034, India  
Mobile: +91-98105-21400, Tel: +91-11-42208000, 8111, 8222, Fax: +91-11-42208444  
Email: customerservice@lifetechindia.com, www.atlabs.com, www.lifetechindia.com

## Tetracyclines ELISA, Microtiter Plate

Enzyme-Linked Immunosorbent Assay for the Determination of Tetracyclines in Contaminated Samples

Product No. 52254BA

### 1. General Description

The Tetracyclines ELISA is an immunoassay for the detection of Tetracyclines. This test is suitable for the quantitative and/or qualitative detection of Tetracyclines in contaminated samples. Positive samples should be confirmed by HPLC, GC/MS, or other conventional methods.

### 2. Safety Instructions

The standard solutions in this test kit contain small amounts of Tetracyclines in solution. In addition, the substrate solution contains tetramethylbenzidine and the stop solution contains diluted sulfuric acid. Avoid contact of standard and stopping solutions with skin and mucous membranes. If these reagents come in contact with the skin, wash with water.

### 3. Storage and Stability

The Tetracyclines ELISA Kit should be stored in the refrigerator (4–8°C) prior to use. The solutions must be allowed to reach room temperature (20–25°C) before use. Reagents may be used until the expiration date on the box. Some reagents need to be stored frozen after reconstitution (Test Preparation, section C).

### 4. Test Principle

The test is a direct competitive ELISA based on the recognition of Tetracyclines by specific antibodies. Tetracyclines, when present in a sample and a Tetracyclines-enzyme conjugate compete for the binding sites of anti-Tetracyclines antibodies which are immobilized on the wells of the microtiter plate. After a washing step and addition of the substrate solution, a color signal is produced. The intensity of the blue color is inversely proportional to the concentration of Tetracyclines present in the sample. The color reaction is stopped after a specified time and the color is evaluated using an ELISA reader. The concentrations of the samples are determined by interpolation using the standard curve constructed with each run.

### 5. Limitations of the Tetracyclines ELISA, Possible Test Interference

Numerous organic and inorganic compounds commonly found in samples have been tested and found not to interfere with this test. However, due to the high variability of compounds that might be found in samples, test interferences caused by matrix effects can not be completely excluded. Mistakes in handling the test can also cause errors. Possible sources for such errors can be:

Inadequate storage conditions of the test kit (**or reagents**), incorrect pipetting sequence or inaccurate volumes of the reagents, too long or too short incubation times during the immune and/or substrate reaction, extreme temperatures during the test performance (lower than 10°C or higher than 30°C).

The Abraxis Tetracyclines ELISA kit provides screening results. As with any analytical technique (GC, HPLC, etc.), positive samples requiring some action should be confirmed by an alternative method.

## Working Instructions

### A. Materials Provided

1. Microtiter plate coated anti-Tetracyclines antibody, in a resealable foil pouch with desiccant.
2. Tetracycline Standards (6): 0, 0.10, 0.20, 0.30, 0.40, 0.60 and 0.80 ng/mL; Control at 0.50 ng/mL. Standard and Control vials supplied lyophilized, 1 mL/vial after reconstitution.
3. Assay Buffer, 6 mL.
4. Sample Diluent (10X) Concentrate, 2 X 25 mL bottles, must be diluted before use. Use to dilute samples.
5. Tetracyclines-HRP Conjugate, 2 vials (lyophilized).
6. Conjugate Diluent, 2 bottles, 12 mL each.
7. Wash Solution (5X) Concentrate, 100 mL.
8. Color (Substrate) Solution (TMB), 16 mL.
9. Stop Solution, 12 mL.

## B. Additional Materials (not included with the test kit)

1. Micro-pipettes with disposable plastic tips (10-200 and 200-1000  $\mu\text{L}$ )
2. Multi-channel pipette (50-250  $\mu\text{L}$ ) or stepper pipette with plastic tips (10-250  $\mu\text{L}$ )
3. Microtiter plate reader (wave length 450 nm)
4. Timer
5. Tape or Parafilm
6. Glass vials with Teflon-lined caps
7. Distilled or deionized water
8. Vortex mixer

## C. Test Preparation

Micro-pipetting equipment and pipette tips for pipetting the standards and the samples are necessary. We recommend using a multi-channel pipette or a stepping pipette for adding the assay buffer, conjugate, substrate and stop solutions in order to equalize the incubations periods of the solutions on the entire microtiter plate. Please use only the reagents and standards from one package lot in one test, as they have been adjusted in combination.

1. Adjust the microtiter plate and the reagents to room temperature before use.
2. Remove the number of microtiter plate strips required from the foil bag. The remaining strips should be stored in the foil bag and zip-locked closed. Store the remaining kit in the refrigerator (4-8°C).
3. The standards, assay buffer, substrate, and stop solutions are ready to use and do not require any further dilutions.
4. The conjugate provided is lyophilized (2 vials). Before each assay, calculate the volume of conjugate needed (when reconstituted, each vial will provide enough conjugate for 1 plate. Once reconstituted, the conjugate solution will only remain viable for 4 weeks (store -20 °C). If additional samples are to be analyzed greater than one week from reconstitution, a new vial of conjugate must be prepared. To reconstitute, add 1 mL of Conjugate Diluent to each vial of Conjugate required and vortex thoroughly then further dilute in the same Conjugate Diluent (**refer to the notice slip that was included in the kit**).
5. The standards and control are provided lyophilized. To reconstitute, add 1.0 mL of deionized water to each vial and vortex thoroughly. Once reconstituted, the standards/control solutions will only remain viable for 4 weeks if stored at -20 °C. Additional vials are available upon request.
6. Dilute the sample diluent (10X) concentrate at a ratio of 1:10. If using the entire bottle (25 mL), add to 225 mL of deionized or distilled water.
7. Dilute the wash buffer (5X) concentrate at a ratio of 1:5. If using the entire bottle (100 mL), add to 400 mL of deionized or distilled water.
8. The stop solution should be handled with care as it contains diluted  $\text{H}_2\text{SO}_4$ .

## D. Preparation of Samples

Samples should be analyzed immediately after preparation to prevent adsorption/degradation of the analyte.

### Meat (Chicken, Beef)

1. Weigh 1.0 gm of homogenized meat into a 15 mL plastic centrifuge tube.
2. Add 3.0 mL of a 1:1 Methanol:Mcllvaine pH 7.0 buffer, vortex thoroughly. Mix using an overhead rotator for 40 minutes.
3. Centrifuge for 10 min at 2,000 X g. Save supernatant.
4. Dilute supernatant 1:20 (i.e. 50  $\mu\text{L}$  of supernatant and 950  $\mu\text{L}$  of 1X Sample Diluent). Vortex to mix and analyze as sample (Assay Procedure, step1).

The Tetracyclines concentration contained in meat samples is then determined by multiplying the ELISA result by the dilution factor of 80. Recoveries were 80-110%

### Milk

1. Dilute milk sample 1:40 (50  $\mu\text{L}$  into 1950  $\mu\text{L}$ ) in 1X sample diluent.
2. Analyze as sample (Assay Procedure, step 1).

The Tetracyclines concentration contained in milk samples is then determined by multiplying the ELISA result by the dilution factor of 40. Recoveries were 100-120%

### Honey

1. Add 0.5 g of honey to a clean plastic tube.
2. Add 19.5 mL of Sample Diluent (1X). Vortex until honey is completely dissolved.
3. Analyze as sample (Assay Procedure, step 1).

**NOTE:** Centrifugation at 3,000 RPM for 5-10 minutes will help with samples exhibiting precipitates.

The Tetracyclines concentration contained in honey samples is then determined by multiplying the ELISA result by the dilution factor of 40. Recoveries were 101-136%.

### Shrimp

1. Weigh 1.0 gm of homogenized meat into a 15 mL plastic centrifuge tube.
2. Add 3.0 mL of 80% Methanol, vortex thoroughly. Mix using an overhead rotator for 20 minutes.
3. Centrifuge for 10 min at 2,000 X g. Pipette 2 mL of the supernatant into clean vial.
4. Centrifuge extract for 10 minutes at 2000 X g. Pipette 1 mL of supernatant into clean vial.
4. Dilute supernatant 1:10 (i.e. 100  $\mu\text{L}$  of supernatant and 900  $\mu\text{L}$  of 1X Sample Diluent). Vortex to mix and analyze as sample (Assay Procedure, step1).

The Tetracyclines concentration contained in shrimp samples is then determined by multiplying the ELISA results by the dilution factor of 40. Recoveries were 114%

**NOTE:** Highly contaminated samples (those outside of the calibration range of the assay) must be diluted further in 1X Sample Diluent and re-analyzed. Samples with values below the first standard should not be multiplied and reported as < 0.10 ppb.

## Water

Prior to analysis, each sample must be filtered using a 0.2  $\mu\text{m}$  polysulfone filter and diluted with 10x Sample Diluent to a 1x final concentration of Sample Diluent (i.e. 100  $\mu\text{L}$  of 10x Sample Diluent into 900  $\mu\text{L}$  of sample).

The Tetracyclines concentration contained in water samples is then determined by multiplying the ELISA results by the dilution factor of 1.11.

## Preparation of Mcllvain Buffer

1. Prepare a 0.2M Sodium Dibasic solution: 28.4 g of  $\text{Na}_2\text{HPO}_4$  to 1 L of deionized water
2. Prepare 0.1M Citric Acid: 29.4 g of Citric Acid Trisodium salt to 1L of deionized water.
3. Adjust pH to 7.0 with 6N Sodium Hydroxide
4. Dilute 1:1 with Methanol before use.

## E. Working Scheme

The microtiter plate consists of 12 strips of 8 wells, which can be used individually for the test. The standards must be run with each test. Never use the values of standards which have been determined in a test performed previously.

### Std 0-Std 6: Standards

0; 0.10; 0.20; 0.30; 0.40; 0.60 ; 0.80 ppb

### Control

### Samp1, Samp2, etc.: Samples

	1	2	3	4	5	6	7	8	9	10	11	12
A	Std 0	Std 4	Samp 1									
B	Std 0	Std 4	Samp 1									
C	Std 1	Std 5	Samp 2									
D	Std 1	Std 5	Samp 2									
E	Std 2	Std 6	etc.									
F	Std 2	Std 6	etc.									
G	Std 3	Control										
H	Std 3											

## F. Assay Procedure

1. Add 50  $\mu\text{L}$  of **assay buffer solution** to the individual wells successively using a multi-channel pipette or a stepping pipette.
2. Add 100  $\mu\text{L}$  of the **standard solutions and samples or sample extracts** into the wells of the test strips according to the working scheme given. We recommend using duplicates or triplicates.
3. Add 50  $\mu\text{L}$  of **enzyme conjugate solution** to the individual wells successively using a multi-channel pipette or a stepping pipette.
4. Cover the wells with parafilm or tape and mix the contents by moving the strip holder in a circular motion on the benchtop for 30 seconds. Be careful not to spill contents.
5. Incubate the strips for 60 minutes at room temperature.
6. After incubation, remove the covering and vigorously shake the contents of these wells into a sink. Wash the strips **four times** using the 1X washing buffer solution. Use 250  $\mu\text{L}$  of washing buffer for each well and each washing step. Remaining buffer in the wells should be removed by patting the plate dry on a stack of paper towels.
7. Add 150  $\mu\text{L}$  of **substrate (color) solution** to the wells. Cover the wells with parafilm or tape and mix the contents by moving the strip holder in a circular motion on the benchtop for 30 seconds. Incubate the strips for 30 minutes at room temperature. Protect the strips from direct sunlight.
8. Add 100  $\mu\text{L}$  of **stop solution** to the wells in the same sequence as for the substrate solution.
9. Read the absorbance at 450 nm using a microplate ELISA photometer within 15 minutes after the addition of the stopping solution.

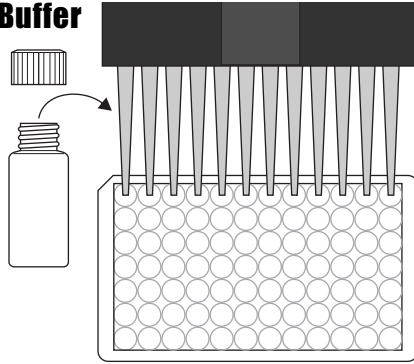
## G. Evaluation

The evaluation of the ELISA can be performed using commercial ELISA evaluation programs [4-Parameter (preferred) or Logit/Log]. For manual evaluation, calculate the mean absorbance value for each of the standards. Calculate the  $\%B/B_0$  for each standard by dividing the mean absorbance value for each standard by the Zero Standard (Standard 0) mean absorbance. Construct a standard curve by plotting the  $\%B/B_0$  for each standard on the vertical linear (y) axis versus the corresponding Tetracycline concentration on the horizontal logarithmic (x) axis on graph paper.  $\%B/B_0$  for samples will then yield levels in ppb of Tetracyclines by interpolation using the standard curve. Samples showing lower concentrations of Tetracyclines compared to Standard 1 (0.10 ng/mL) should be reported as containing < 0.10 ng/mL. Samples showing a higher concentration than Standard 6 (0.80 ng/mL) must be diluted further to obtain accurate results.

# Tetracyclines Plate, Detailed ELISA Procedure

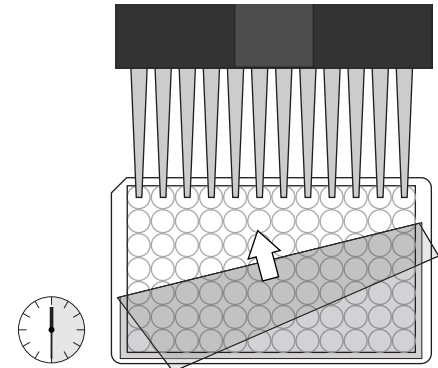
## 1. Addition of Assay Buffer

Add 50  $\mu$ l of Assay Buffer to the wells of the test strips successively using a multi-channel pipette or a stepping pipette according to the working scheme given. We recommend using duplicates or triplicates.



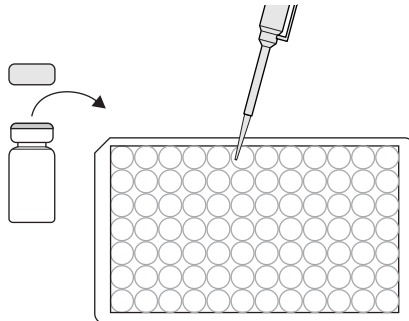
## 5. Addition of Substrate/Color Solution

Add 150  $\mu$ l of substrate/color solution to the individual wells successively using a multi-channel pipette or a stepping pipette. Cover the wells with parafilm or tape and mix the contents by moving the strip holder in a rapid circular motion on the benchtop. Be careful not to spill contents. Incubate the strips for 20-30 min at room temperature.



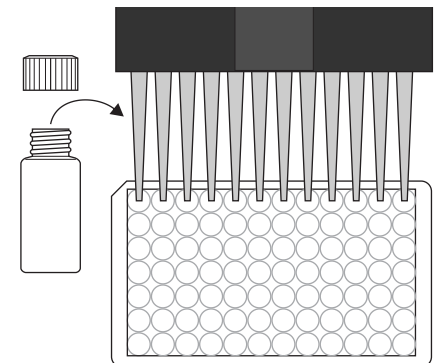
## 2. Addition of Standards, Samples

Add 100  $\mu$ l of the standard solutions, control, or samples to the wells of the test strips according to the working scheme given.



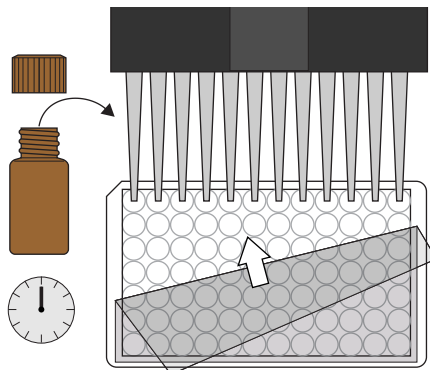
## 6. Addition of Stopping Solution

Add 100  $\mu$ l of stop solution to the wells in the same sequence as for the substrate solution using a multi-channel pipette or a stepping pipette.



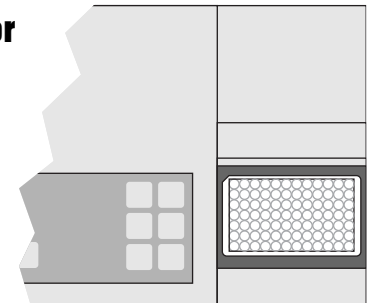
## 3. Addition of Conjugate Solution

Add 50  $\mu$ l of the enzyme conjugate to the individual wells successively using a multi-channel pipette or a stepping pipette. Cover the wells with parafilm or tape and mix the contents by moving the strip holder in a rapid circular motion on the benchtop. Be careful not to spill contents. Incubate the strips for 60 min at room temperature.



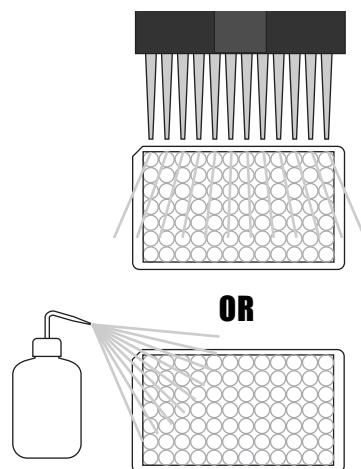
## 7. Measurement of Color

Read the absorbance at 450 nm using a microplate ELISA reader. Calculate results.



## 4. Washing of Plates

After incubation, remove the covering and vigorously shake the contents of the wells into a sink. Wash the strips four times with a multi-channel pipette or wash bottle using the diluted 1X washing buffer solution. Please use at least a volume of 250  $\mu$ l of washing buffer for each well and each washing step. Remaining buffer in the wells should be removed by patting the plate dry on a stack of paper towels.



India Contact:

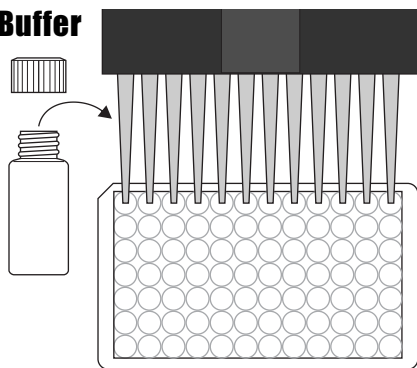
**Life Technologies (India) Pvt. Ltd.**

306, Aggarwal City Mall, Road No. 44, Pitampura, Delhi - 110034, India  
Mobile: +91-98105-21400, Tel: +91-11-42208000, 8111, 8222, Fax: +91-11-42208444  
Email: customerservice@lifetechindia.com, [www.atzlabs.com](http://www.atzlabs.com); [www.lifetechindia.com](http://www.lifetechindia.com)

# Tetracyclines Plate, Concise ELISA Procedure

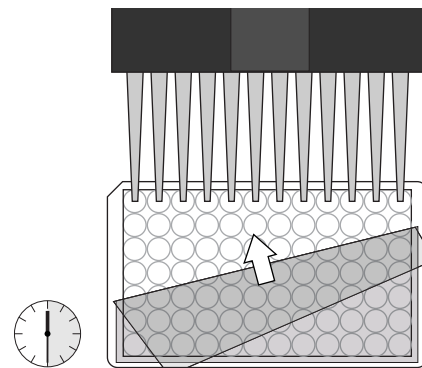
## 1. Addition of Assay Buffer

Add 50  $\mu$ l of Assay Buffer.



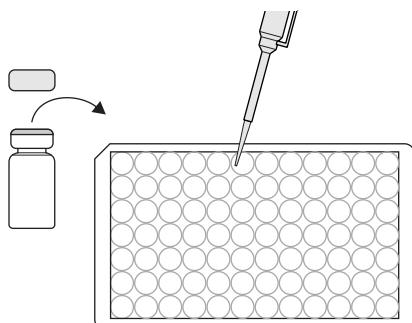
## 5. Addition of Substrate/Color Solution

Add 150  $\mu$ L of substrate/color solution. Incubate 20-30 minutes at room temperature and away from direct sunlight.



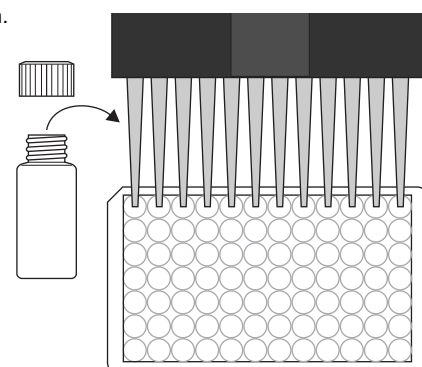
## 2. Addition of Standards, Samples

Add 100  $\mu$ l of the standard solutions, control, or samples.



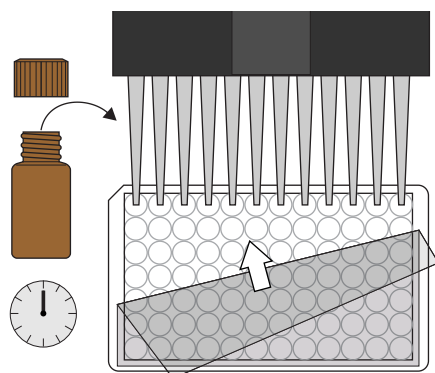
## 6. Addition of Stopping Solution

Add 100  $\mu$ L of stop solution.



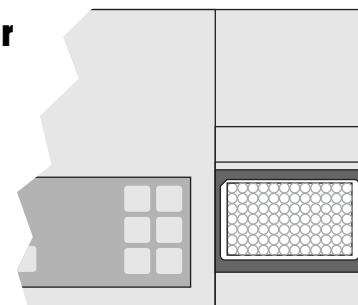
## 3. Addition of Conjugate Solution

Add 50  $\mu$ L of the enzyme conjugate. Cover and mix for 30 seconds by rotating on benchtop. Incubate for 60 min at room temperature.



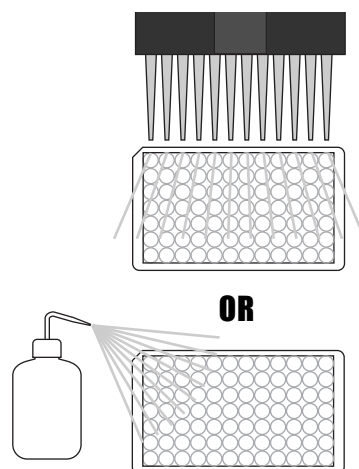
## 7. Measurement of Color

Measure color at 450 nm. Calculate results.



## 4. Washing of Plates

Wash the plates four times with 250  $\mu$ L of diluted 1X washing buffer.



India Contact:

**Life Technologies (India) Pvt. Ltd.**

306, Aggarwal City Mall, Road No. 44, Pitampura, Delhi - 110034, India

Mobile: +91-98105-21400, Tel: +91-11-42208000, 8111, 8222, Fax: +91-11-42208444

Email: [customerservice@lifetechindia.com](mailto:customerservice@lifetechindia.com), [www.atzlabs.com](http://www.atzlabs.com); [www.lifetechindia.com](http://www.lifetechindia.com)



# Safety Data Sheet

## Section 1: Product and Company Identification

### 1.1 Product Identifiers:

**Product Name:** Tetracyclines/Epimers ELISA Plate Kit

**Product Code:** 52254BA

**1.2 Identified Use:** Determination of Tetracyclines/Epimers in samples. **Restrictions on Use:** For research use only.

**1.3 Company:** Abraxis, Inc., 124 Railroad Drive, Warminster, PA 18974 USA, [info@abraxiskits.com](mailto:info@abraxiskits.com) +1(215) 357-3911, FAX +1(215) 357-5232

**1.4 Emergency Telephone Number:** +1(215) 357-3911

## Section 2: Hazard(s) Identification

**2.1 Classification of the mixture:** Not a hazardous mixture.

**2.2 GHS Label elements, including precautionary statements:** Not applicable.

**2.3 Hazards not otherwise classified (HNOC) or not covered by GHS:** None known.

**2.4 Unknown acute toxicity:** None known.

## Section 3: Composition / Information on Ingredients

**3.2 Mixtures:** *Contains no hazardous ingredients at levels requiring disclosure by the OSHA Hazard Communication Standard (29 CFR 1910.1200), however it contains minor amounts of materials considered hazardous. We recommend handling all substances with caution.*

## Section 4: First Aid Measures

**4.1 Description of first aid measures:** Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

**If inhaled:** If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

**In case of skin contact:** Wash off with soap and plenty of water. Consult a physician.

**In case of eye contact:** Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

**If swallowed:** Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

**4.2 Most important symptoms and effects, both acute and delayed:** No data available

**4.3 Indication of any immediate medical attention and special treatment needed:** No data available. Treat symptomatically.

## Section 5: Fire-fighting Measures

**5.1 Suitable extinguishing media:** Use an extinguishing agent suitable for the surrounding fire.

**5.2 Special hazards arising from the substance or mixture:** None known

**5.3 Advice for firefighters:** Wear self-contained breathing apparatus for fire-fighting if necessary.

**5.4 Further information:** No data available

## Section 6: Accidental Release Measures

**6.1 Personal precautions, protective equipment and emergency procedures:** Use personal protective equipment (see section 8). Avoid dust formation. Avoid breathing vapors, mist, dust, or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

**6.2 Environmental precautions:** Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

**6.3 Methods and materials for containment and cleaning up:** Solids (if applicable): Pick up and arrange disposal without creating dust. Sweep up and shovel. Liquids (if applicable): Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Keep in suitable, closed containers for disposal.

**6.4 Reference to other sections:** For information on safe handling see section 7.

For information on personal protection see section 8.

For information on disposal see section 13.

## Section 7: Handling and Storage

**7.1 Precautions for safe handling:** See section 2. Avoid inhalation of vapors and contact with skin and eyes. Wear appropriate personal protective equipment. Do not eat, drink, or smoke in work area.

**7.2 Precautions for safe storage:** Keep container(s) tightly closed in a dry, well-ventilated place. Protect from physical damage. See label or product insert for appropriate storage temperature and additional specific information.

7.3 Specific end use(s): No data available

## Section 8: Exposure Controls / Personal Protection

**8.1 Control parameters:** Not applicable.

**8.2 Exposure controls:**

**Appropriate engineering controls:** Provide adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday. Keep away from food and beverages.

**Personal protective equipment:** The usual precautionary measures, including eye/face/skin protection, should be taken when handling any chemical. Avoid contact with eyes, skin, and clothing.

**Eye protection:** As with handling of any chemical, wear approved safety goggles.

**Skin protection:** Handle with gloves. No specific information regarding glove material or thickness is available, but gloves must be impermeable and resistant to the substance being handled. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

**Respiratory protection:** As with any chemical, where excessive vapor, mist, or dust may result, use a chemical fume hood or approved respiratory protection equipment.

**Body protection:** Lightweight, protective clothing.

## Section 9: Physical and Chemical Properties

**9.1 Information on basic physical and chemical properties of the mixture**

**Appearance:** Multiple

**Odor:** Characteristic

**Odor Threshold:** No data available

**pH:** Multiple

**Melting point/freezing point:** No data available

**Initial boiling point and boiling range:** No data available

**Flash point:** Not applicable

**Evaporation rate:** No data available

**Flammability (solid, gas):** No data available

**Upper/lower flammability or explosive limits:** No data available

**Vapor pressure:** No data available

**Vapor density:** No data available

**Relative density:** No data available

**Water solubility:** Various

**Partition coefficient: n-octanol/water:** No data available

**Auto-ignition temperature:** Not applicable

**Decomposition temperature:** No data available

**Viscosity:** No data available

**Explosive properties:** No data available

**Oxidizing properties:** No data available

**9.2 Other information:** No data available

## Section 10: Stability and Reactivity

**10.1 Reactivity:** No data available

**10.2 Chemical stability:** Stable under recommended storage conditions.

**10.3 Possibility of hazardous reactions:** No data available

**10.4 Conditions to avoid:** No data available

**10.5 Incompatible materials:** No data available

**10.6 Hazardous decomposition products:** No data available. In the event of fire: see section 5.

## Section 11: Toxicological Information

**11.1 Information on toxicological effects**

**Acute toxicity:** Not available. To the best of our knowledge, the chemical, physical, and toxicological properties of this product have not been thoroughly investigated.

**Inhalation:** No data available      **Ingestion:** No data available

**Skin contact:** Irritant to skin and mucous membranes.

**Eye contact:** May cause eye irritation in susceptible persons.

**Respiratory or skin sensitization:** No data available

**Aspiration hazard:** No data available

**Mutagenicity:** No data available

**Carcinogenicity**

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

**Teratogenicity:** No data available

**Reproductive/fertility toxicity:** No data available

**Specific target organ toxicity, single exposure:** No data available

**Specific target organ toxicity, repeated exposure:** No data available

## Section 12: Ecological Information

**12.1 Toxicity:** No data available

**12.2 Persistence and degradability:** No data available

**12.3 Bioaccumulative potential:** No data available

**12.4 Mobility in soil:** No data available

**12.5 Results of PBT and vPvB assessment:** No data available

**12.6 Other adverse effects:** An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

## Section 13: Disposal Considerations

### 13.1 Waste treatment methods

**Product:** All waste must be handled and disposed according to local, state, and federal regulations. Avoid disposing large volumes in sewer.

**Contaminated packaging:** All waste must be handled and disposed according to local, state, and federal regulations.

Refer to sections 7 and 8 for safe handling guidance.

## Section 14: Transport Information

**UN Number:** Not regulated

**UN Proper shipping name:** Not classified as dangerous in the meaning of transport regulations.

**Transport hazard class(es):** No data available

**Packing group:** No data available

**Environmental hazard:** No data available

**Bulk transport:** No data available

**Special considerations:** No data available

## Section 15: Regulatory Information

To the best of our knowledge, this product contains no substances which, at their given concentrations, are considered hazardous by other regulatory agencies. Refer to section 3.

## Section 16: Other information

This information is based on our present knowledge. While Abraxis, Inc. believes that the data contained herein are factual and the opinions expressed represent a best effort to present accurate information, the data are not to be taken as a warranty or representation for which Abraxis, Inc. assumes legal responsibility. The information shall not be taken as being all-inclusive and is to be used only as a guide. The data are offered solely for the user's consideration, investigation, and verification. These suggestions should not be confused with either state, municipal, or insurance requirements, or with national safety codes and constitute no warranty. Any use of these data and information must be determined by the user to be in accordance with applicable federal, state, and local regulations.

All materials and mixtures may present unknown hazards and should be used with caution. Since Abraxis, Inc. cannot control the methods, volumes, or conditions of use of this product, Abraxis, Inc. shall not be held liable for any damages or losses resulting from the handling or from contact with the product as described herein. An individual technically qualified to handle potentially hazardous chemicals must supervise the use of this material. This product is sold for research use only. It is not for any human or animal therapeutic or clinical diagnostic use.

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**Changes from previous version:** Abraxis, LLC changed to Abraxis, Inc.