

Certificate

Certificate No.: MD 1243914-1-1

Manufacturer: **DRG International., Inc.**

841 Mountain Avenue
Springfield NJ 07081
USA

REPs Facility ID: F003033

Certification criteria: ISO 13485:2016

Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure

Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021,
RDC ANVISA n. 67/2009

Canada Medical Devices Regulations – Part 1 – SOR 98/282,

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D

Scope: Design and development, manufacture and distribution of in-vitro diagnostic test kits used in the diagnosis or detection of transmissible agents and sexually transmissible agents, cancer, prenatal screening, immune status, disease status, autoimmune status, drugs of abuse, cardiac markers, cardiovascular disease, endocrine disorders, fertility testing, pregnancy testing and the design and development, installation and service of in-vitro diagnostic analyzers.

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 1194196-690

Issue Date: 2025-10-23

Effective Date: 2025-11-02

Expiry Date: 2028-11-01



Certification officer: Dr. Matthias Fischer
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on <https://www.certipedia.com> or calling 1-888-743-4652.



Instructions for Use



DE-TOX TUBES A&B



DTL 109A/DTL 109B



100 Tubes



Legal Manufacturer:

DYNA-TEK INDUSTRIES
Lenexa
KS 66215
USA

Distributed by:



DRG Instruments GmbH, Germany
Division of DRG International, Inc
Frauenbergstr. 18, D-35039 Marburg
Telefon: +49 (0)6421-17000
Fax: +49-(0)6421-1700 50
Internet: www.drg-diagnostics.de
E-mail: drg@drg-diagnostics.de

1 INTRODUCTION

1.1 Intended Use

DE-TOX Tubes are intended for efficient extraction of a wide spectrum of drugs and their metabolites including drugs of abuse. DE-TOX Tubes have been formulated in such a way that they provide consistent and maximum extraction of a large number of drugs.

DE-TOX Tubes can be used to extract drugs from urine..

DE-TOX Tubes are available as **DE-TOX Tubes A (#DTL 109A)** and **DE-TOX Tubes B (#DTL 109B)**.

DE-TOX Tubes A are intended for the extraction of basic and neutral drugs such as analgesics, stimulants, tranquilizers, antidepressants and other classes of drugs.

DE-TOX Tubes B are intended for the extraction of acidic and neutral drugs such as barbiturates and other hypnotics.

2 PRINCIPLE OF THE TEST

DE-TOX Tubes A & B are liquid/liquid extraction tubes for the extraction of drugs in urine for various analytical methods, such as Thin-layer Chromatography or GC/MS.

3 WARNINGS AND PRECAUTIONS

- The DE-TOX Tubes extraction procedure works with various analytical methods. The results obtained may vary depending on the technique and/or procedure used to process the sample extracted with DE-TOX Tubes.
- Do not use DE-TOX Tubes if the solvent level is below the line marked on the front of the tube.

4 REAGENTS

4.1 Reagents provided

100 DE-TOX Tubes A (DTL 109A) or 100 DE-TOX Tubes B (DTL 109B).

4.1.1 Material required but not provided

- Centrifuge (2500 rpm)

4.2 Storage conditions

When stored at room temperature unopened tubes will retain reactivity until expiration date.

4.3 Reagent preparation

Shake or tap the A tubes to loosen the salt mixture at the bottom before adding the specimen.

5 SPECIMEN COLLECTION AND PREPARATION

Urine samples can be used for extraction with DE-TOX Tubes A & B.

6 PROCEDURE

1. Allow specimens to come to room temperature before adding to the tubes.
2. Add 5 mL of urine specimen to DE-TOX Tubes A or 4,5 mL of urine specimen to DE-TOX Tubes B to the 'FILL LINE' printed on the tubes.
3. Cap the tubes tightly and shake for at least 2 to 5 minutes.
4. Centrifuge the tubes for at least 5 minutes at a minimum speed of 2500 rpm.

The colorless top organic layer in the DE-TOX Tubes containing extracted drugs can be aspirated and drugs concentrated by evaporation of the solvent.

The extracted drugs can be separated, detected and identified by any of the many analytical techniques available.

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 1170693-1
Certificate Holder: DRG Instruments GmbH
Frauenbergstr. 18
35039 Marburg
Germany

Scope: Design and development, manufacture and distribution of in-vitro diagnostic test kits used in the diagnosis or detection of transmissible agents and sexually transmissible agents, cancer, prenatal screening, immune status, disease status, autoimmune status, drugs of abuse, cardiac markers, protein metabolism, endocrine disorders, compatibility testing, fertility testing, pregnancy testing, therapeutic drug monitoring and design and development, installation and service of in-vitro diagnostic analyzers.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1180489-100
Effective date: 2025-04-03
Expiry date: 2028-04-02
Issue date: 2025-03-27
Replaces certificate SX 1170693-1 issued 2022-04-26

This certificate can be validated on <https://www.certipedia.com>


M.Sc. Irene Carraretto
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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DRG Drug Screening

TOXI-LAB®

Drug Identification Systems-Detection and Identification of more than 700 drugs from urine, serum or gastric specimens in less than 1 hour.

- Standardized Thin Layer Chromatography
- Reproducible, analyte specific results
- Drug compendium for quick, accurate and reliable drug identification
- Intl.Version of the drug compendium
- Proficiency Service
- Liquid/Liquid Extractions for DC/HPLC/GCMS



TOXI•LAB®

Thin-Layer Chromatography Products and Accessories

TOXI-LAB AB

TOXI-LAB AB System is a unique and rapid thin-layer chromatographic system designed for broad spectrum drug detection and drug confirmation.

The Initial TOXI-LAB AB System comes complete with hardware and supplies for TOXI-LAB A (100 tests) for the detection of organic base and neutral drugs and TOXI-LAB B (100 tests) for the detection of barbiturates and some other acidic/neutral drugs.

Cat. No.TL 100AB-100

Supplies

- 100 TOXI GRAMS A
- 100 TOXI GRAMS B
- 100 TOXI GRAMS Blank A
- 100 TOXI GRAMS Blank B
- 100 TOXI TUBES A
- 100 TOXI TUBES B
- 500 Disposable Concentration Cups
- 200 TOXI DISCS Blank A
- 200 TOXI DISCS Blank B
- 2 Vials TOXI DIP A-3 Reagent Concentrate
- 2 Sets TOXI DIP B Reagent Concentrates
- 6 TOXI CONTROLS, one each of 1, 2, 3, and 5; two each of 19
- 0.5 Liter Ethyl Acetate, TOXI-LAB Grade
- 100 Worksheets A
- 100 Worksheets B

Accessories

- 1 Module I, Workstation / Storage Tray
- 1 Module II, Workstation
- 1 Module III, Ultraviolet Light Unit
- 1 Drummond Microdispenser
- 1 Custom Electric Warmer
- 1 Heat Gun
- 1 Heat Gun Holder
- 1 Ultraviolet Light
- 1 Ammonium Hydroxide Vial with Cap
- 1 Omega-12 Extraction Solvent Concentrator and Screen
- 1 Chromatography Jar with Cap
- 4 Stock Reagent Bottles
- 2 Developing Solution Bottles
- 6 Dipping Jars with Special Caps
- 1 Standoff Jar
- 1 Extra Storage Jar Cap
- 1 Forceps
- 3 Disc-Handling Pins
- 2 TOXI RACK 3 Sets

Reference Aids

- 1 TOXI-LAB AB Instruction Manual
- 1 TOXI-LAB Drug Compendium
- 1 Set TOXI-LAB Training Programs (2 Programs in Set)

Services

Basic Workshop

TOXI-LAB A-PLUS

TOXI-LAB A-PLUS is a rapid thin-layer chromatographic method for the detection and identification of basic and neutral drugs.

This initial System is complete with hardware and supplies for those laboratories who do not currently have the TOXI-LAB AB System and require high volume throughput.

Cat. No. TL400A-I I

Supplies

- 50 TOXI GRAMS Blank A-PLUS
- 100 TOXI TUBES A
- 100 TOXI DISCS Blank A
- 50 TOXI DISCS A-1
- 50 TOXI DISCS A-2
- 50 TOXI DISCS A-3
- 50 TOXI DISCS A-4
- 6 Vials TOXI DIP A-3 Reagent Concentrate
- 500 Disposable Concentration Cups
- 6 TOXI Controls, one each of 1, 2, 3 and 5; two each of 19
- 0.5 Liter Ethyl Acetate, TOXI-LAB Grade
- 50 TOXI GRAMS PLUS Worksheets

Accessories

- 1 Module I, Workstation / Storage Tray
- 1 Custom Electric Warmer
- 1 Heat Gun
- 1 Heat Gun Holder
- 1 Ammonium Hydroxide Vial with Cap
- 1 Omega-12 Extractor Solvent Concentrator and Screen

TOXI-LAB B-PLUS

TOXI-LAB B-PLUS is a rapid thin-layer chromatographic method for the detection and identification of acidic and neutral drugs.

This initial System is complete with hardware and supplies for those laboratories who do not currently have the TOXI-LAB AB System and require high volume throughput.

Cat. No. TL400B-I I

Supplies

- 50 TOXI GRAMS Blank B-PLUS
- 100 TOXI TUBES B
- 100 TOXI DISCS Blank B
- 50 TOXI DISCS B-1
- 50 TOXI DISCS B-2
- 50 TOXI DISCS B-3
- 50 TOXI DISCS B-4
- 6 Vials TOXI DIP B Reagent Concentrate (B-1, B-2, B-3)
- 500 Disposable Concentration Cups
- 2 TOXI Controls, one each of 3 and 19
- 0.5 Liter Ethyl Acetate, TOXI-LAB Grade
- 50 TOXI GRAMS PLUS (11) Worksheets

Accessories

- 1 Module I, Workstation / Storage Tray
- 1 Custom Electric Warmer
- 1 Heat Gun



(Accessories cont 'd)

- 1 TOXI-LAB Chromatography Tank and Lid
- 1 Developing Solution Bottle
- 1 Stock Reagent Bottle (A-3)
- 1 TOXI DIP A-1 Reagent Standoff Jar (Large)
- 1 TOXI DIP A-2 Reagent Tank and Lid
- 1 TOXI DIP H₂O Reagent Tank and Lid
- 1 TOXI DIP A-3 Reagent Tank and Lid
- 3 TOXI DIP Chromatogram Stands
- 1 Forceps
- 3 Disc-Handling Pins

Reference Aids

- 1 TOXI-LAB AB Instruction Manual
- 1 TOXI-LAB Drug Compendium
- 1 Set TOXI-LAB Training Programs (2 Programs in Set)

Services

Basic Workshop



(Accessories con 't)

- 1 Heat Gun Holder
- 1 Ammonium Hydroxide Vial with Cap
- 1 Omega-12 Extractor Solvent Concentrator and Screen
- 1 TOXI-LAB Chromatography Tank and Lid
- 1 Developing Solution Bottle
- 3 Stock Reagent Bottle (B-1, B-2, B-3)
- 1 TOXI DIP B-1 Reagent Tank and Lid
- 1 TOXI DIP B-2 Reagent Tank and Lid
- 1 TOXI DIP B-3 Reagent Tank and Lid
- 1 TOXI DIP Chromatogram Stand
- 1 Forceps
- 3 Disc-Handling Pins

Reference Aids

- 1 TOXI-LAB AB Instruction Manual
- 1 TOXI-LAB Drug Compendium

Services

Basic Workshop

DRG Drug Screening

TOXI-LAB AB-PLUS

Initial Systems

TOXI-LAB AB-PLUS is the same product in principle as the TOXI-LAB System but uses larger (PLUS) chromatograms, allowing more samples to be tested per chromatogram. These systems are complete with hardware and supplies for those laboratories who do not currently have the TOXI-LAB AB System and require high volume throughput.

Cat. No. TL400AB-I I

This system consists of the following:

Cat. No. TL400A-I I

TOXI LAB A-Plus Initial System

Cat. No. TL420B-I I

TOXI LAB A-Plus Conversion Pack

TOXI-LAB THC II

TOXI-LAB THC II is a rapid thin-layer chromatographic method for marijuana metabolite, Δ -THC-COOH, in urine.

TOXI-LAB THC II may be used by hospital, reference, and forensic laboratories to screen or confirm the presence of Δ -THC-COOH in urine \geq 15 ng/mL. Contains supplies sufficient for 100 tests.

Cat. No. TL261

Supplies

- 25 TOXI GRAMS Blank THC II (3-Channel)
- 100 SPEC-C18-I Extraction Cartridges with Sample Reservoirs
- 50 TOXI DISCS THC
- 500 Disposable Concentration Cups
- 2 Vials TOXI DIP THC-I Reagent Concentrate
- 2 30-mL Bottles of Hydrolysis Reagent
- 1 50 mL Bottle of TOXI CONTROL THC
- 100 Worksheets, THC II (3-Channel)

Accessories

- 1 Custom Electric Warmer (not pictured)
- 1 Omega-12 Extraction Solvent Concentrator and Screen
- 2 Chromatography Jars with Caps
- 1 TOXI DIP Reagent Jar (THC-I)
- 1 HCl Standoff Jar with Cap
- 1 Small Standoff Jar with Cap (TOXI DIP THC-2 Reagent)
- 1 THC Developing Solution Bottle
- 1 Wash-Reagent-1 Bottle
- 1 Wash-Reagent-2 Bottle
- 1 Forceps
- 3 Disc-Handling Pins

TOXI-LAB AB-PLUS

(11-Channel TOXI GRAMS)

Supplies

- 100 TOXI TUBES B
- 100 TOXI DISCAS Blank B
- 50 TOXI DISCS B-1
- 50 TOXI DISCS B-2
- 50 TOXI DISCS B-3
- 50 TOXI DISCS B-4
- 6 Sets TOXI DIP B
Reagent Concentrate (B-1, B-2, B-3)



Reference Aids

- 1 TOXI-LAB THC II Instruction Manual with Color Detection Guides

Services

Basic Workshop

TOXI-LAB THC II-PLUS

TOXI-LAB THC II-PLUS is an extension of TOXI-LAB THC II that employs larger chromatograms, TOXI GRAMS Blank THC II-PLUS (11), for simultaneous analysis of up to 10 specimens. Contains supplies sufficient for 200 tests. Cat. No. TL262

Supplies

- 50 TOXI GRAMS Blank THC II (11-Channel)
- 200 SPEC-C18-I Extraction Cartridges with Sample Reservoirs
- 50 TOXI DISCS THC
- 4 Vials TOXI DIP THC-I Reagent Concentrate
- 4 30-mL Bottles of Hydrolysis Reagent
- 1 50 mL Bottle of TOXI CONTROL THC
- 100 Worksheets, THC II (11-Channel)

Accessories

- 1 Custom Electric Warmer
- Omega-12 Extraction Solvent Concentrator
- 1 Chromatography Tank with Lid
- 1 Reagent Tank with Lid (for TOXI DIP THC-I Reagent)
- 2 TOXI DIP Reagent Tanks with Lids and Standoffs (for TOXI DIP THC-2 Reagent and HCl Reagent)
- 1 THC Developing Solution Bottle
- 1 Wash-Reagent-1 Bottle
- 1 Wash-Reagent-2 Bottle
- 1 Forceps

TOXI-LAB LTD Opiate

The TOXI-LAB LTD Opiate Initial System is for low threshold detection (200 ng/mL) and differentiation of morphine, codeine, hydrocodone, hydromorphone, and dihydrocodeine. Cat. No. TL310

Supplies

- 20 TOXI GRAMS LTD Blank Opiate
- 20 TOXI DISCS LTD OP
- 20 TOXI DISCS LTD HD
- 20 TOXI DISCS LTD OPI
- 100 TOXI DISCS LDT Blank O
- 2 TOXI CONTROL LTD FM
- 100 SPEC LTD MP3¹ Columns
- 500 Disposable Concentration Cups
- 100 LTD Opiate Devel. Sol. I Worksheets
- 100 LTD Opiate Devel. Sol II Worksheets

Accessories

- 1 Module I (Workstation/Storage Tray)
- 1 Drummond Microdispenser
- 1 Custom Electric Warmer
- 1 Heat Gun
- 1 Heat Gun Holder
- 1 Ammonium Hydroxide Vial with Cap
- 1 Omega-12 Extraction Solvent Concentrator and Screen
- 2 Chromatography Jars with Cap



Reference Aids

- 1 TOXI-LAB THC II Instruction Manual with Color Detection Guides

Services

Basic Workshop



(Accessories cont 'd)

- 1 Developing Solution I Bottle
- 1 Developing Solution II Bottle
- 1 Wash Reagent Bottle
- 1 Elution Reagent Bottle
- 1 1M Acetic Acid Reagent Bottle
- 1 TOXI DIP A-2 Reagent Jar
- 1 TOXI DIP H₂O Reagent Jar
- 1 Forceps
- 3 Dis-Handling Pins

Reference Aids

- 1 LTD Opiate System Instruction Manual and Color Detection Guides

Services

Basic Workshop

1) A vacuum system is required for use of this product (see page 67)

DRG Drug Screening

TOXI-LAB A-PLUS

Conversion Pack

This product is for existing TOXI-LAB AB customers needing to expand the number of tests per analysis using TOXI-LAB A.
Cat. No. TL420A-11

Supplies

- 50 TOXI GRAMS Blank A-PLUS
- 50 TOXI GRAMS PLUS Worksheets

Accessories

- 1 TOXI-LAB Chromatography Tank and Lid
- 1 TOXI DIP A-2 Reagent Tank and Lid
- 1 TOXI DIP H₂O Reagent Tank and Lid
- 1 TOXI DIP A-3 Reagent Tank and Lid
- 3 TOXI DIP Chromatogram Stands
- 1 Large Standoff Jar



Reference Aids

- 1 TOXI-LAB AB Instruction Manual

TOXI-LAB B-PLUS

Conversion Pack

This product is for existing TOXI-LAB AB customers needing to expand the number of tests per batch using TOXI-LAB B.
Cat. No. TL420B-11

Supplies

- 50 TOXI GRAMS Blank B-PLUS (11) (500 tests)
- 50 TOXI GRAMS PLUS (11) Worksheets

Accessories

- 1 TOXI-LAB Chromatography Tank and Lid
- 3 Stock Reagent Bottles (B-1, B-2, B-3)
- 1 TOXI DIP B-1 Reagent Tank and Lid
- 1 TOXI DIP B-2 Reagent Tank and Lid
- 1 TOXI DIP B-3 Reagent Tank and Lid
- 1 TOXI DIP Chromatogram Stand



Reference Aids

- 1 TOXI-LAB AB Instruction Manual

TOXI-LAB LTD Opiate

Starter Pack

Basic LTD Opiate Starter Pack supply package for laboratories who currently use the TOXI-LAB AB System. 100 tests/pk
Cat. No.TL319

Supplies

- 20 TOXI GRAMS LTD Blank Opiate
- 20 TOXI DISCS LTD OP
- 20 TOXI DISCS LTD HD
- 20 TOXI DISCS LTD OPI
- 100 TOXI DISCS LDT Blank O
- 2 TOXI CONTROL LTD FM
- 100 SPEC LTD MP3⁺ Columns
- 500 Disposable Concentration Cups
- 100 LTD Opiate Devel. Sol. I Worksheets
- 100 LTD Opiate Devel. Sol II Worksheets
- 1 Developing Solution I bottle
- 1 Developing Solution II bottle
- 1 Wash Reagent bottle
- 1 Elution Reagent bottle
- 1 1M Acetic Acid Reagent bottle

A vacuum system is required for the extraction of analytes where SPEC•Solid Phase Extraction columns are used.

TOXI•LAB THC II and LTD•Opiate systems employ SPEC•columns. The following vacuum products and equipment are efficient and effective for use in performing solid phase extractions.

Solid Phase Extraction Vacuum System A580

This system provides all the equipment required for processing SPEC•column extractions and includes the Solid Phase Extraction Vacuum Manifold (Cat. No.A581), 115V, 60Hz Vacuum Pump (Cat. No. A582), and Vacuum Trap Assembly (Cat. No.A584). See individual catalog numbers for details.

Solid Phase Extraction Vacuum System A580i

Identical to Cat. No.A580, but uses the 230V AC, 50 Hz Vacuum Pump (Cat. No.A583).



Reference Aids

- 1 LTD Opiate System Instruction Manual and Color Detection Guides

Solid Phase Extraction Vacuum System A581

This manifold allows simultaneous extraction of up to 12 samples using the SPEC•Solid Phase Extraction columns. Precise flow control is provided by simply rotating the independent, screw-type valves built into the cover, eliminating the need for separate stopcock valves.

The clear glass chamber allows observation of fluids as they pass through the SPEC•columns. The polypropylene collection-vessel rack is adaptable for use with the aluminum TOXI•LAB Disposable Concentration Cups (Cat. No.A152) or various collection tubes. A vacuum gauge is included with this unit.

Dimensions: Length, 8 1/4 in; Width, 4 1/2 in; Height, 7 1/2 in.
Shipping weight: 8 lbs (approximate)

TL 580 Solid Phase Extraction Vacuum System

DRG Drug Screening

PACKS

TOXI-LAB®

Cat. No.	Product Description	Unit
TL 102A-50	TOXI-PACK A 50	50 Tests/pack
TL 102B-50	TOXI-PACK B 50	50 Tests/pack

CHROMATOGRAMS

TOXI-LAB®

Cat. No.	Product Description	Unit
TL 106A	TOXI-GRAMS A-100	100 Chromatograms/pack
TL 120A	TOXI-GRAMS Blank A-100	100 Chromatograms/pack
TL 405	TOXI-GRAMS Blank A-PLUS (11)	50 Chromatograms/pack
TL 417	TOXI-GRAMS Blank A-PLUS (19)	50 Chromatograms/pack
TL106B-100	TOXI-GRAMS B-100	100 Chromatograms/pack
TL 120B-100	TOXI-GRAMS Blank B-100	100 Chromatograms/pack
TL 421	TOXI-GRAMS Blank B-PLUS (11)	50 Chromatograms/pack
TL 256	TOXI-GRAMS Blank THC II (3-Channel)	25 Chromatograms/pack
TL 255	TOXI-GRAMS Blank THC II-PLUS (11-Channel)	50 Chromatograms/pack
TL 209-100	TOXI-GRAMS Blank THC	100 Chromatograms/pack
TL 311-100	TOXI-GRAMS Blank LTD Opiate (6-Channel)	100 Chromatograms/pack
TL 312-20	TOXI-GRAMS LTD (6 Channel)	20 Chromatograms/pkg

EXTRACTION SUPPLIES

TOXI-LAB®

Cat. No.	Product Description	Unit
TL 109A-100	TOXI-TUBES A-100	100 Tubes/pack
TL 109B-100	TOXI-TUBES B-100	100 Tubes/pack
TL 251	SPEC-C18-I	100 /pack
TL 475	Hydrolysis Tubes	50 /pack
TL 210	THC Disposable Glass Tubes	50 Tubes/pack
TL 320	SPEC LTD MP-3 SPEC	100/pack
TL 475	Hydrolysis Tubes with Caps	50 /pack