

# For Diagnostics Manufacturers



**genzyme**  
Diagnostics

In today's healthcare environment, finding the right supplier is a critical decision. With nearly three decades of experience, quality products and dedicated support, Genzyme Diagnostics is the one supplier you can trust to understand what is expected and essential for your specific needs.

Genzyme Diagnostics' unique portfolio focuses on three strategic product lines:

- Diagnostic intermediates (critical raw materials)
- Clinical chemistry reagents
- Point-of-care rapid tests

As an industry leader, Genzyme Diagnostics maintains close relationships with hospitals, clinics, physicians' offices, reference, alternative-care facilities and medical research labs throughout the world. If you choose Genzyme Diagnostics, you can count on us . . . now and in the future.

# Genzyme Diagnostics

## WHO WE ARE

As Genzyme Diagnostics approaches its 28th year of existence, I'd like to take a few moments to discuss who Genzyme Diagnostics is. Established in 1981, Genzyme Diagnostics was the very first division of Genzyme Corporation, a global healthcare and biotechnology leader with more than 11,000 employees worldwide. Since then, we have been supplying our customers a variety of products and services with the goal of introducing solutions to unmet medical diagnostic needs.

Genzyme Diagnostics has developed unique products in three strategic areas: Diagnostic Intermediates (critical raw materials) clinical chemistry reagents and point-of-care rapid tests. They are manufactured and packaged in ISO 13485 certified and QSR-compliant facilities in Kent, UK, Framingham, MA, Prince Edward Island, Canada, and San Diego, CA.

Our ability to research, develop, formulate, package, and support products has propelled Genzyme Diagnostics to leadership positions across our product lines. For example, our strong core competency in microbial fermentation, purification, and reagent formulation allows us to supply more than 50 intermediate products to chemistry instrument manufacturers; the more than 60 clinical reagents we make are used on chemistry analyzers worldwide; and thousands of laboratories rely on our cardiovascular products, like homogeneous HDL and LDL, not to mention our diagnostic products used to analyze diabetic, renal, liver, and pancreatic function.

Finally, our OSOM® rapid test products are focused on infectious diseases and women's health. Genzyme Diagnostics plays an important role in the movement towards personalized medicine by developing tests that can help physicians quickly and accurately diagnose their patients in order to provide the most appropriate treatment.

I invite you to use this guide as a quick reference. For a more comprehensive review of our products, visit [www.genzymediagnosics.com](http://www.genzymediagnosics.com)

We are proud of the impact Genzyme Diagnostics has had in the lives of countless people around the world and we hope you will allow us the opportunity to demonstrate our quality, commitment and support in meeting your needs.

Sincerely,

DONALD E. POGORZELSKI  
PRESIDENT

# Genzyme Diagnostics

## YOUR PARTNER OF CHOICE

When choosing a supplier for your reagent or critical raw material needs, in today's clinical market it is imperative that your partner of choice can provide the necessary experience, quality products, dedicated support, and trust you require. At Genzyme Diagnostics we fully understand what is expected and essential for your business. You can count on us.

### EXPERIENCE

As an industry leader, we currently enjoy relationships with manufacturers, distributors and medical research laboratories worldwide. You can be assured Genzyme Diagnostics will be there to effectively respond to your needs and requirements, now and in the future.

### QUALITY

At Genzyme Diagnostics we are committed to quality products and customer satisfaction. We operate according to the highest quality standards and are fully compliant with international quality standards. Genzyme's principle manufacturing and production facilities are ISO 13485 certified and compliant to QSR regulations. You can be assured that your reagents and diagnostic tests are consistently monitored for quality — as raw materials, work-in-process, final finished products and retained samples. Our facilities adhere to strict formulation, quality control, and quality assurance procedures, which guarantee lot-to-lot consistency and specific product performance characteristics, time after time, test after test.

Genzyme reagents and critical raw materials have a documented history of field proven performance and reliability in some of the most demanding environments around the world.

### OPPORTUNITIES

It's a proven fact that successful products stem from successful partnerships. That is why if you are considering selecting an outsourcing partner for your OEM or custom

manufacturing needs, you need to consider Genzyme. It is imperative there is understanding, trust, and confidence between partners.

### SUPPORT

When current and potential customers approach us with challenges and issues requiring unique solutions, we follow a proven approach to address them. The Genzyme Diagnostics commitment to your facility or office runs deep in terms of involvement, support and resource dedication. We recognize that to provide a full solution for your diagnostic and reagent needs, our support must be as reliable and consistent as our products.

Genzyme Diagnostics Customer Service Representatives are trained to process your orders promptly and precisely. It is their responsibility to ensure your orders arrive complete and on time.

Our Technical Support Group is comprised of skilled professionals and medical technologists, many with extensive clinical laboratory experience. Their responsibilities include telephone assistance, field support, product training, and scientific development, vital functions that are all performed with skill.

The Genzyme Diagnostics Sales Support Group represents industry professionals with extensive backgrounds. You can always rely on them for answers on a host of topics:

- Technical product information
- Multi-lingual instructions for use
- Material Safety Data Sheets (MSDS)
- Certificates of Analysis, Certificates of Origin
- Product comparison data
- Answers to "Frequently Asked Questions"
- Promotional/educational support material
- Educational websites
- Sales and marketing advice
- On-line product training

# Genzyme Diagnostics

## WHAT WE DO FOR YOU

### CLINICAL CHEMISTRY REAGENTS

A comprehensive menu of precision reagents ensures the right match of tests for optimum performance from your chemistry analyzer. An extensive listing of assays currently exists for lipid, cardiac, general, special, and renal testing. All Genzyme reagents feature inherent benefits that many others claim, but those you are sure to find with Genzyme Diagnostics include:

**Liquid Stable Technology** — Many of our Genzyme reagents are available as stable liquids — simply open the bottle and you are ready to go. Problems associated with reconstitution procedures, pipetting errors and water quality are eliminated, saving time, labor, and reagent waste.

**Exceptional Performance** — The performance characteristics of Genzyme Diagnostics reagents are exceptional with regard to accuracy, precision, linearity and stability. These features help eliminate repeat testing and maximize instrument uptime, saving time, labor, and unnecessary expense.

**Accommodating Packaging** — With laboratory refrigeration space at a premium, it's vital to have reagents in a packaging format that is both economical and easily integrated into laboratories. Genzyme Diagnostics reagents feature operator oriented, compact packaging that can be customized to meet your needs. Regardless of laboratory size or workload, a packaging configuration is available that fits your requirements.

**Supporting Products and Services** — An extensive offering of supporting products and services is available, including calibration materials, standards, quality control products, and various programs. This allows for convenient ordering and regulatory compliance and simplifies QC management.

**Applications** — Genzyme Diagnostics currently maintains and oversees more than 2,000 validated instrument applications and suggested testing guidelines for use on most major chemistry instrument platforms. Genzyme Diagnostics maintains a number of in-house instruments for quality control, application development, technical support, and validation testing work. We can develop and provide specific applications on an as needed basis — just another example of the Genzyme Diagnostics commitment to your business.

### CRITICAL RAW MATERIALS

In addition to our reagents we offer an extensive portfolio of high quality critical raw materials. Our primary customers are diagnostic reagent and biosensor manufacturers, particularly those focused on cardiovascular disease, diabetes, renal function, pancreatitis, and liver function.

**Lot-to-Lot Consistency** — Our dedicated highly trained assay technicians ensure that every single lot of material is released only when specifications have been met. Many of our customers rely fully on the Genzyme release analysis to directly formulate their final products.

**Customization Possibilities** — If our critical raw materials don't exactly meet your requirements we are open to discussions regarding customization of labeling, additional quality control release testing, packaging, product format and product properties. These are subject to return on investment.

**Technical Support** — Our Technical Support Group is also supported by our Research and Development scientists who are available to answer your questions regarding application and formulation of products should you require assistance.

## Clinical Chemistry Reagents



### ABOUT THE PRODUCT LINE

Genzyme Diagnostics is a recognized leader in the development, manufacture, and supply of innovative reagents and assays systems to the IVD industry.

Our broad line of chemistry reagents currently exists for lipid, cardiovascular, general, special, and renal testing. All reagents feature liquid stable technology, exceptional performance, accommodating packaging, field-proven performance, along with supporting products and services.

In addition, our replacement chemistries are economical and a number of applications are available for many automated analyzers.

# Clinical Chemistry Reagents

DIAGNOSTIC USE	PRODUCT	ATTRIBUTES
Toxicology	Acetaminophen L3K®	Enzymatic (Acyl-Aminohydrolase) assay Stable liquid Reduced NAC interference
Toxicology	Acetaminophen-SL	Enzymatic (Acyl-Aminohydrolase) assay
Liver Disease	Alanine Aminotransferase (ALT/SGPT) L3K®	Enzymatic (Modified IFCC) assay Two part stable liquid
Liver Disease	Alanine Aminotransferase (ALT/SGPT) -SL	Enzymatic (Modified IFCC) assay One part stable liquid Significant linear range of 5-800 U/L
Liver/Kidney Disease	Albumin	Bromcresol Green (BCG) assay Stable liquid
Liver Disease	Alkaline Phosphatase (ALP)-SL	Enzymatic (p-Nitrophenylphosphate) assay Stable liquid
Liver Disease	Ammonia L3K®	Enzymatic (Glutamate Dehydrogenase) assay One part stable liquid No significant interference from ascorbic acid or bilirubin
Pancreatitis	Amylase Direct	Enzymatic (CNP3) assay Stable liquid Direct method eliminates delays due to extended lag phase
Liver Disease	Aspartate Aminotransferase (AST/SGOT)-SL	Enzymatic (Modified IFCC) assay Stable liquid
Liver Disease	Bilirubin, Direct-SL	DCA assay Stable liquid
Liver Disease	Bilirubin, Total L3K®	DCA assay Stable liquid Serum or plasma acceptable Neonatal serum samples acceptable Significantly reduced hemolytic and lipemic interferences
Metabolic Disorder	Calcium	Arsenazo III assay Stable liquid Excellent precision
Metabolic Disorder	Calcium L3K®	Phosphonazo assay Stable liquid Environmentally friendly, arsenic free
Metabolic Disorder	Carbon Dioxide (CO2) L3K®	Enzymatic (Phosphoenolpyruvate Carboxylase) assay Stable liquid Good correlation to ISE methods
Metabolic Disorder	Carbon Dioxide (CO2) L3K® Concentrate	Enzymatic (Phosphoenolpyruvate Carboxylase) assay Stable liquid Concentrated (5x)
Cardiovascular	Cholesterol, Total-SL	Enzymatic (Cholesterol Esterase/Oxidase) assay Stable liquid
Cardiovascular	Ultra N-geneous® HDL Cholesterol Reagent	Accelerator Selective Detergent assay Stable liquid Meets NCEP total error goals of <13% Serum or plasma acceptable

Please note that some products listed may not be available internationally.

# Clinical Chemistry Reagents

DIAGNOSTIC USE	PRODUCT	ATTRIBUTES
Cardiovascular	N-geneous® LDL Cholesterol Reagent	Accelerator Selective Detergent assay Stable liquid Meets NCEP total error goals for both normal and high triglyceride samples Serum or plasma acceptable No fasting required
Immunology	N-geneous® wrCRP Reagent	Immunturbidimetric assay Stable liquid Increased sensitivity at low concentrations Extended linear range
Cardiovascular	Creatine Kinase (CK)-SL	Enzymatic (NAC Activated) assay Stable liquid Extended linear range (2-1500 U/L)
Kidney Disease	Creatinine, Enzymatic	Enzymatic (Creatinine Amidohydrolase) assay Stable liquid Non hazardous reagent Increased linearity Serum, plasma and urine acceptable
Kidney Disease	Creatinine-S	Modified Jaffé assay Stable liquid
Kidney Disease	Cystatin C	Colloidal Gold assay Stable liquid Excellent precision and accuracy Serum or plasma acceptable
Toxicology	Ethanol L3K®	Enzymatic (Alcohol Dehydrogenase) assay One part stable liquid Serum, plasma and urine acceptable
Liver Disease	Gamma Glutamyl-Transferase (GGT)	Enzymatic (Carboxy Substrate/Modified IFCC) Kinetic assay Stable liquid Serum or plasma acceptable
Diabetes	Glucose	Enzymatic (Glucose Oxidase) assay Reconstituted reagent is stable for 30 days at 2-8° C
Diabetes	Glucose-SL	Enzymatic (Hexokinase) assay Stable liquid
Anemia	Iron, Total-PC (Protein Clearing)	Ferrozine® assay Reduced paraprotein interference Suitable for protein containing serum and lithium heparin plasma
Anemia	Iron, Total-SL	Ferene® assay Stable liquid
Liver/Cardiovascular Disease	Lactate Dehydrogenase (LDH)-SL	Enzymatic (Lactate→Pyruvate) assay Stable liquid
Pancreatitis	Lipase Color Kit	Enzymatic (1,2 Diglyceride) assay Excellent precision Wide linear range
Pancreatitis	Liquid N-geneous® Lipase Reagent	Enzymatic assay Stable liquid Open vial stability up to 60 days (AMERICAS ONLY)

# Clinical Chemistry Reagents

DIAGNOSTIC USE	PRODUCT	ATTRIBUTES
Diabetes/Kidney Disease	Magnesium	Xylidyl Blue assay Stable liquid Extended linear range: 0.5-6.1 mg/dL
Kidney Disease	Microalbumin	Immunturbidimetric assay Stable liquid
Kidney Disease	Micro-Total Protein	Pyrogallol Red assay Stable liquid Urine or cerebrospinal fluid acceptable
Kidney Disease	Phosphorus, Inorganic-SL	Ammonium Molybdate assay Stable liquid Wide Linear Range: 0.1-20 mg/dL
Toxicology	Salicylate-SL	Enzymatic (Salicylate Hydroxylase) assay Stable liquid
Liver Disease	Sorbitol Dehydrogenase (SDH)	Enzymatic; Kinetic assay For Veterinary Use Only
Liver/Kidney Disease	Total Protein	Biuret assay Stable liquid
Cardiovascular	Triglyceride-SL	Enzymatic (Glycerol Phosphate Oxidase) assay Stable liquid Wide Linear Range: 3.0 mg/dL to 1000.0 mg/dL
Anemia	Unsaturated Iron Binding Capacity (UIBC)	Ferene <sup>®</sup> ; Endpoint assay Stable liquid Exceptional high end linearity (600 µg/dL)
Kidney Disease	Urea (BUN) L3K <sup>®</sup>	Enzymatic (Urease) assay Stable liquid
Kidney Disease	Uric Acid-SL	Enzymatic (Uricase) assay Stable liquid Wide Linear Range: 0.3 mg/dL to 20.0 mg/dL

Please note that some products listed may not be available internationally.

# Clinical Chemistry Calibrators and Controls

## PRODUCT

Acetaminophen/Salicylate Control Materials Level 1

Acetaminophen/Salicylate Control Materials Level 2

N-geneous™ wrCRP Calibrator (multiple levels)

DC-Cal Multi-Analyte Calibrator

DC-Trol Multi-Analyte Control Material Level 1

DC-Trol Multi-Analyte Control Material Level 2

Ultra N-geneous® HDL Cholesterol Calibrator

N-geneous® LDL ST Calibrator

N-geneous® LDL Cholesterol Calibrator

Lipase Color Calibrator

Liquid N-geneous® Lipase Calibrator

Microalbumin Calibrator

Microalbumin Controls

Sorbitol Dehydrogenase (SDH) Control Material Level 1

Sorbitol Dehydrogenase (SDH) Control Materials Level 2

UIBC Calibrator

# Clinical Chemistry Linearity

## PRODUCT

N-geneous® HDL Linearity Verifier Kit

N-geneous® LDL Linearity Verifier Kit

UIBC Lineate

## Critical Raw Materials

### ABOUT THE PRODUCT LINE

For over 25 years, Genzyme has been a prime manufacturer of critical raw materials, such as enzymes and substrates for the manufacture of clinical chemistry reagents and biosensors. We are a key partner for custom manufacturing.



# Critical Raw Materials by Catalog Number

PRODUCT	SOURCE	INTERNATIONAL	U.S.
<b>DIAGNOSTIC ENZYMES</b>			
1-5-Anhydroglucitol-6-Phosphate Dehydrogenase	<i>Escherichia coli</i>	T-95	T-95
3 $\alpha$ -Hydroxysteroid Dehydrogenase	<i>Pseudomonas sp.</i>	T-58	T-58
3-Hydroxybutyrate Dehydrogenase	<i>Alcaligenes faecalis</i>	T-68	70-6825-01
Acyl-CoA Oxidase	<i>Arthrobacter sp.</i>	T-17	T-17
Acyl-CoA Synthetase	<i>Pseudomonas fragi</i>	T-16	T-16
ADP-dependent Hexokinase	<i>Pyrococcus furiosus</i>	T-92	T-92
ADP-dependent Hexokinase	<i>Thermococcus litoralis</i>	T-93	T-93
Alkaline Phosphatase	<i>Escherichia coli</i>	T-08	T-08
Ascorbate Oxidase	Zucchini	70-6141-20	70-6141-20
Ascorbate Oxidase	<i>Acremonium sp.</i>	T-53	T-53
Bilirubin Oxidase	<i>Myrothecium sp.</i>	70-1021-01	70-1021-01
Bilirubin Oxidase (L)	<i>Bacillus subtilis</i>	T-188	T-188
Catalase (L)	<i>Aspergillus sp.</i>	CATA-70-4004	CATA-70-4004
Cholesterol Dehydrogenase	<i>Nocardia sp.</i>	CHDE-70-1241	CHDE-70-1241
Cholesterol Esterase	<i>Pseudomonas sp.</i>	CHES-70-1041	CHES-70-1041
Cholesterol Esterase	<i>Pseudomonas sp.</i>	T-18	70-6221-01
Cholesterol Esterase	Microorganism	T-98	T-98
Cholesterol Esterase	<i>Candida rugosa</i>	70-6201-01	70-6201-01
Cholesterol Oxidase	<i>Nocardia sp.</i>	CHOX-70-1101	70-1101-01
Cholesterol Oxidase	Microorganism	T-101	T-101
Cholesterol Oxidase (L)	Microorganism	T-84	T-84
Cholesterol Oxidase (R)	<i>Streptomyces lividans</i>	RECO-70-1221	70-1221-02
Choline Oxidase	<i>Arthrobacter globiformis</i>	T-05	T-05
Diaphorase (NADH)	<i>Bacillus megaterium</i>	T-06	70-6311-01
Diaphorase (NADPH)	<i>Bacillus megaterium</i>	T-10	T-10
Glucoamylase	<i>Rhizopus sp.</i>	GLUC-70-6881	GLUC-70-6881
Glucose Dehydrogenase	<i>Bacillus sp.</i>	GLDE-70-1191	70-1191-01
Glucose Oxidase 100:1 (L)	<i>Aspergillus niger</i>	GLOX-70-4854	GLOX-70-4854
Glucose Oxidase HPS100	<i>Aspergillus niger</i>	GLOX-70-6451	70-6451-01
Glucose Oxidase HPS200	<i>Aspergillus niger</i>	GLOX-70-6455	GLOX-70-6455
Glucose Oxidase (L)	<i>Aspergillus niger</i>	GLOX-70-6594	GLOX-70-6594
Glucose-6-Phosphate Dehydrogenase	<i>Leuconostoc mesenteroides</i>	GLPD-70-1201	70-1201-01
Glucose-6-Phosphate Dehydrogenase	<i>Bacillus sp.</i>	T-51	T-51
Glycerol Kinase	<i>Cellulomonas sp.</i>	GLKI-70-6495	GLKI-70-6495

# Critical Raw Materials by Catalog Number

PRODUCT	SOURCE	INTERNATIONAL	U.S.
Glycerol Kinase	<i>Flavobacterium meningosepticum</i>	T-64	T-64
Glycerol Phosphate Oxidase	<i>Pediococcus n.b</i>	70-6051-01	70-6051-01
Glycerophosphorylcholine Phosphodiesterase	<i>Gliocladium roseum</i>	T-33	T-33
Hexokinase	Yeast	HEXO-70-1351	70-1351-01
Hexokinase	<i>Bacillus sp.</i>	T-50	T-50
Hexokinase	<i>Rhodothermus obamensis</i>	T-141	T-141
Ketoamine Oxidase (L)	<i>Fusarium oxysporum</i>	KEOX-70-1264	KEOX-70-1264
Lactate Dehydrogenase	Microbial	LADE-70-1411	LADE-70-1411
Lactate Oxidase (rec.)	<i>Aerococcus viridians</i>	RELO-70-1381	70-1381-01
Lipase	<i>Chromobacterium viscosum Bacillus sp.</i>	T-116	70-6890-01
Lipase	Microorganism	T-63	T-63
Lipase	<i>Chromobacterium viscosum</i>	LIPA-70-1461	70-1461-01
Lysophospholipase	<i>Vibrio sp.</i>	T-32	T-32
L- $\alpha$ -Glycerophosphate Oxidase	<i>Streptococcus sp.</i>	T-60	70-4875-01
L- $\alpha$ -Glycerophosphate Oxidase (R)	<i>Streptococcus sp.</i>	T-107	T-107
Malate Dehydrogenase	Microbial	MADE-70-1521	MADE-70-1521
Maltase ( $\alpha$ -Glucosidase)	Yeast	MALT-70-1235	70-1235-01
Monoglyceride lipase	<i>Bacillus sp.</i>	T-117	T-117
NAD Synthetase	<i>Bacillus stearothermophilus</i>	T-67	T-67
Oxaloacetate Decarboxylase	<i>Pseudomonas sp.</i>	T-14	70-6661-01
Peroxidase RZ 2.0	Horseradish	PERO-70-6915	PERO-70-6915
Phosphofructokinase	<i>Bacillus stearothermophilus</i>	T-119	T-119
Phosphoglucose Isomerase	<i>Bacillus stearothermophilus</i>	T-120	T-120
Phospholipase A2 (L)	<i>Streptomyces violaceoruber</i>	T-184	T-184
Phospholipase C	<i>Bacillus cereus</i>	T-11	T-11
Phospholipase D	<i>Streptomyces chromofuscus</i>	T-07	70-1641-01
Phospholipase D	<i>Streptomyces sp.</i>	T-138	T-138
Proteinase K	<i>Tritirachium album</i>	PROK-70-4825	PROK-70-4825
Purine Nucleoside Phosphorylase (L)	<i>Bacillus sp.</i>	T-69	T-69
Pyruvate Oxidase	<i>Aerococcus viridans</i>	T-45	70-1691-01
Sarcosine Oxidase	<i>Bacillus sp.</i>	T-46	T-46
Tyramine Oxidase	<i>Arthrobacter sp.</i>	T-25	T-25
Urease	Jack bean	UREA-70-1651	UREA-70-1651
Urease (L)	Jack bean	70-6734-01	70-6734-01
Uricase	<i>Bacillus fastidiosus</i>	URIC-70-1701	70-1701-01
Uricase	<i>Candida utilis</i>	70-1711-01	70-1711-01

# Critical Raw Materials by Catalog Number

PRODUCT	SOURCE	INTERNATIONAL	U.S.
Uricase	<i>Arthrobacter globiformis</i>	URIC-70-1721	70-1721-01
Xanthine Dehydrogenase (L)	Microorganism	T-134	T-134
<b>ANTIBIOTIC INACTIVATING ENZYMES</b>			
β-Lactamase (vials)	<i>Bacillus cereus</i>	BELA-70-1401	BELA-70-1401
β-Lactamase II (bulk powder)	<i>Bacillus cereus</i>	BELA-70-1431	70-1431-01
Penicillinase (vials)	<i>Bacillus cereus</i>	PENI-70-1545	PENI-70-1545
Penicillinase (bulk powder)	<i>Bacillus cereus</i>	PENI-70-1541	PENI-70-1541
<b>INTERMEDIATES</b>			
Streptavidin	n/a	STRE-70-4801	STRE-70-4801
Valinomycin	n/a	VALI 997860	VALI 997860
<b>SUBSTRATES FOR AMYLASE DETERMINATION</b>			
CNPG3	n/a	CHNM-70-3821	70-3821-01
BpNPG7	n/a	BLNM-70-3685	70-3685-01



#### **INVESTING IN PEOPLE**

At Genzyme we are driven, first and always, by our commitment to patients. Genzyme exists to innovate on behalf of people with serious diseases and to meet major unmet medical needs. With over 11,000 employees worldwide, the talents, energy, and determination of each Genzyme employee enable us to do this important work. Genzyme recognizes the vital role its employees play and in turn has been selected by FORTUNE magazine as one of the "100 Best Companies to Work For" in the United States.

One of the world's foremost biotechnology companies, Genzyme is dedicated to making a major positive impact on the lives of people with serious diseases. At Genzyme Diagnostics, a business of the Genzyme Corporation, we are committed to quality products and customer satisfaction.

#### **CONTACT INFORMATION**

To discuss opportunities or to place an order:

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