

Formulating
solutions,
delivering
results

genzyme
Diagnostics

Formulating solutions, delivering results



Successful products stem from strong partnerships, so choose Genzyme Diagnostics if you are considering an outsourcing partner for:

- OEM reagent manufacturing
- Reagent or enzyme custom manufacturing
- Enzyme validation and optimization

We fully recognize the importance of flexibility, reliability, adaptability, and customization while working with our partners. From initial product concept and through development, launch and commercialization, we know what is expected and required — you can count on us.

PROVEN EXPERIENCE

For over 29 years, Genzyme Diagnostics has provided its products, services, knowledge, and expertise to the diagnostic and life science industries. As an industry leader, we currently enjoy relationships with many globally recognized diagnostic companies. We welcome the unique challenges that current and potential partners present us with.

PROVEN MANUFACTURING

Reagent Capabilities:

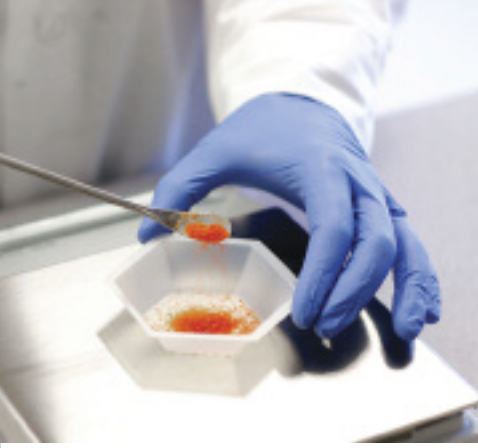
Flexible Manufacturing

- Custom Formulations
- Final Product QC Testing
- Instrument Application Development
- Kit Assembly
- Labeling
- Liquid Formulation & Filling
- Lyophilization
- Packaging Design
- Powder Blending & Filling
- Technology Transfer

Enzyme Capabilities:

Adaptability of Key Raw Materials

- Bioprocessing
- Cell Culture
- Custom Manufacture
- Enzyme Assay Development
- Facility to handle organisms up to ACDP & BSL category 2
- Formulation
- Freeze Drying
- Microbial Fermentation & Optimization
- Protein Purification
- Quality Control Testing
- Scale-up & Manufacturing Transfer
- Tissue Extraction



“Genzyme’s Operations team is dedicated to providing quality products, made right the first time, to customer specifications and expectations.”

*Tracey Jewells-Treige
Director of Operations, P.E.I.
15 years with Genzyme Diagnostics
(and the former Diagnostic
Chemicals Limited)*



PROVEN QUALITY

Our products are consistently monitored for quality from the raw material and in-process stage to final finished product and retained samples. Genzyme Diagnostics facilities adhere to strict formulation, quality control and quality assurance procedures, which guarantee lot-to-lot consistency and specific product performance characteristics.

PROVEN COMPLIANCE

In addition to our commitment to achieving total product quality, Genzyme Diagnostics manufacturing facilities maintain registration to ISO9001 or ISO13485:2003 quality standards and are compliant to QSR regulations. Quality, consistency, and documented performance take top priority. Our facilities are also subject to audit and inspection by numerous governing regulatory agencies.

PROVEN SUPPORT

Genzyme Diagnostics recognizes that to achieve the desired results for your outsourcing needs, our support must be an integral part of the process. Our employees are dedicated professionals with extensive IVD industry experience. By drawing on individuals from various departments with the appropriate skills and backgrounds, we assemble a working business team dedicated to understanding your specifications, your product and your needs. Together we can formulate solutions and deliver results.

- Genzyme Diagnostics manages projects through its Program Management group.
- This group is made up of highly experienced staff working with cross functional teams at your organization and within our own company.
- Program Managers construct project timelines and milestones to ensure clear goals and timeline visibility.



"Our dedicated personnel and robust manufacturing processes ensure we deliver a quality product to you that will work consistently every time."

*Darren Ladd
Director of High Volume Manufacturing
24 years with Genzyme Diagnostics*



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