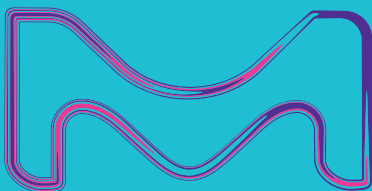


diagnostic elite

Millipore
SIGMA

Critical raw materials for mitigating
risk in IVD manufacturing



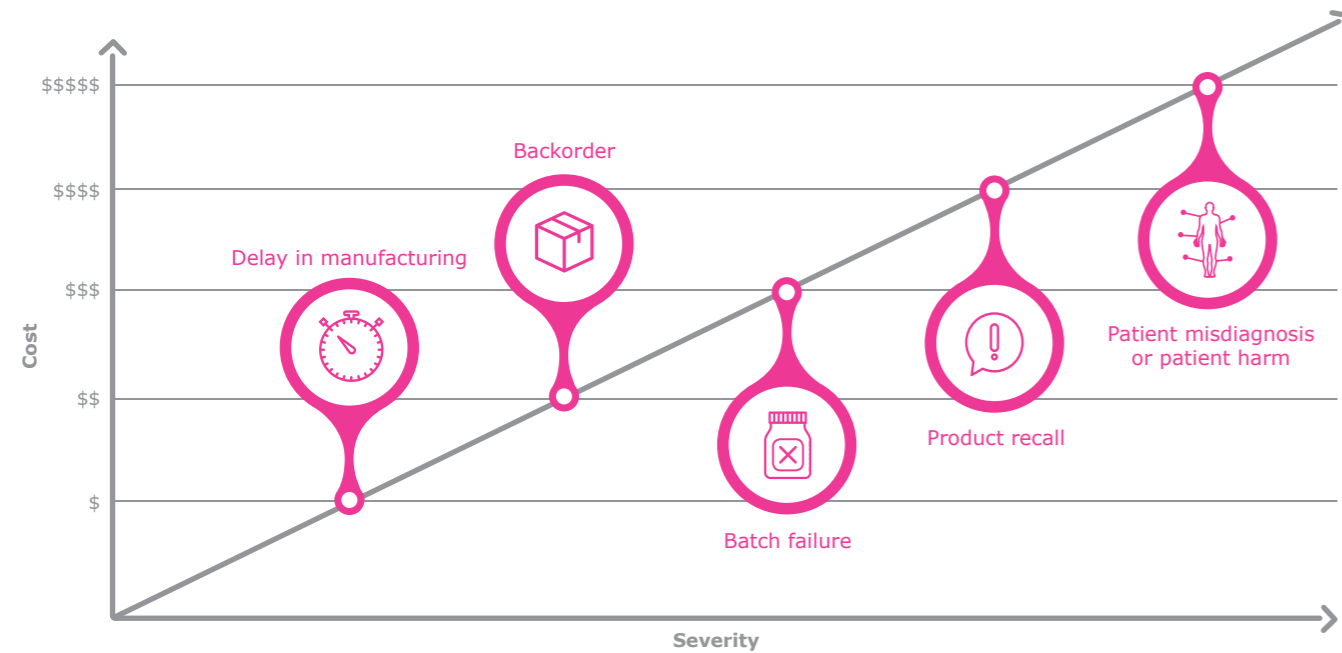
The life science business of Merck KGaA,
Darmstadt, Germany operates as MilliporeSigma
in the U.S. and Canada.

Mitigate risk & increase consistency

Invest in your future product security and proactively mitigate risk. The Diagnostic Elite program is more than a set of raw materials.

Your development and manufacturing of IVD assays is a complex process involving:

- Critical raw material requirements.**
 Appropriate product selection is key to avoiding disruptions in assay design, delays in manufacturing, and impact on assay performance.
- Evolving IVD industry regulations.**
 Create a requirement for enhanced supplier support.



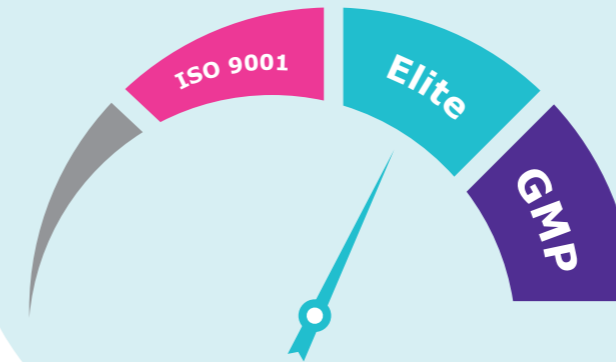
The **Diagnostic Elite** program was developed as an enhanced portfolio of raw materials with your IVD manufacturing needs in mind. Every Diagnostic Elite raw material is designed to promote consistency across your entire assay production process, with the goal of improving manufacturing effectiveness while minimizing your level of risk.

The Diagnostic Elite program leverages our knowledge of IVD industry regulations, manufacturing, quality and supply chain management to provide you with the required level of support to meet your IVD manufacturing requirements.

With a better understanding of the raw material attributes of Elite products, you can proactively choose products that best meet your current and future manufacturing needs.

Align quality to criticality

Raw materials of higher criticality have increased quality expectations.



The Elite Quality Grade

We have developed the **Elite** quality grade to offer nearly all GMP quality attributes without the associated cost burden. IVD market feedback indicates that the **Elite** grade is a good fit for critical raw material usage, balancing the need for **consistency, transparency** and **control**, against price.

Our Enhanced Quality Guidelines below outline the different levels of quality, documentation and supply chain traceability that we can provide to diagnostic manufacturers.

Our Enhanced Quality Guidelines

Attributes	Standard	Premium	Diagnostic Elite Products	
			Elite	GMP
Product Use	Research, Industrial and Chemical Specialities	Research, Industrial and Chemical Specialities	IVD Manufacturing and Biopharma Processing	API, BPE, IVD, Biopharma Applications
Raw Material Regulatory Requirements	Non-Regulated Applications	Non-Regulated Applications	Regulated Applications	Regulated Applications
Quality Systems Controls	ISO 9001	ISO 9001	ISO 9001 plus other Controlled Processes	ICH Q7, IPEC, 21 CFR, ISO 13485
Sourcing Information	Proprietary	Discretionary Confidential Information Shared Under CDA	Confidential Information Shared Under CDA	Confidential Information Shared Under CDA
Analytical Methods	•	•	•	•
Certificate of Analysis	•	•	•	•
Change Control Notification	•	•	•	•
Product Specification	•	•	•	•
Certificate of Origin		•	•	•
Expiry or Retest Date		•	•	•
Vendor Assessment		•	•	•
Critical Control Parameter			•	•
QA Batch Review			•	•
Lot Sample Retained			•	•
Vendor Management			•	•
Validation				•

Change Control Management & Notification

We are committed to maintaining consistent manufacturing processes for Diagnostic Elite and GMP products.

We understand that changes in critical raw materials may require an IVD manufacturer to perform extensive impact analysis and validation. To reduce this risk and communicate changes in a time frame that would limit the impact to commercialization, we have implemented:

- Change controls
- Enhanced change notifications

When changes are unavoidable, we are committed to providing you with earlier advanced notification.

The times indicated below are the minimum length of advance notification you would receive.

Timeline of Notification Prior to Change

Example Notifiable Events	Diagnostic Elite Products			
	Standard	Premium	Elite	GMP
Expiry or Recommended Retest Date	Immediate	Immediate	Immediate	Immediate
Storage Temperature	Immediate	Immediate	Immediate	Immediate
EQP Status Downgrade	N/A	Immediate	Immediate	Immediate
Product Recalls and Alerts	Immediate	Immediate	Immediate	Immediate
Product Master Data (Name, formula weight, CAS#, etc.)	Immediate	Immediate	Immediate	Immediate
Label Changes (CAS#, formula, storage temp, weights)	Immediate	Immediate	Immediate	Immediate
Vendor (company we place our PO with)	2 weeks	4 weeks	12 weeks	12 weeks
Country of Origin (in-house manufactured)	2 weeks	4 weeks	12 weeks	12 weeks
Manufacturing Site (in-house manufactured)	2 weeks	4 weeks	12 weeks	12 weeks
Analytical Release Specifications and/or Methods	2 weeks	4 weeks	12 weeks	12 weeks
Site - Packaging	2 weeks	4 weeks	12 weeks	12 weeks
Site - Finished Product Testing Laboratory	2 weeks	4 weeks	12 weeks	12 weeks
Primary Packaging Materials (only catalogue packaging; not applicable to custom packaging)	N/A	4 weeks	12 weeks	12 weeks
Country of Origin (procured items)	N/A	4 weeks	12 weeks	12 weeks
Shipping and Handling	N/A	4 weeks	12 weeks	12 weeks
Type of Manufacture	N/A	4 weeks	12 weeks	12 weeks
Biologic Country of Origin for Starting Material (animal sourced only)	N/A	N/A	12 weeks	12 weeks
Manufacturing Site (procured)	N/A	N/A	12 weeks	12 weeks
Significant Manufacturing Process Changes	N/A	N/A	12 weeks	12 weeks

The Early Access Program (EAP)

Through the Diagnostic Elite portfolio and EAP, our goal is to develop enhanced, reliable products that meet your critical raw material requirements.

As the Diagnostic Elite program expands, we continue to work diligently to align new and optimized products with your evolving needs. One key approach is our Early Access Program (EAP). Through the EAP, we provide the opportunity for IVD manufacturers to collaborate with us in selecting and designing specifications of new Diagnostic Elite products.

The program provides collaborating diagnostic manufacturers with:

- Exclusive early access to new Diagnostic Elite products
- The opportunity to influence product development through testing and feedback
- Alignment of product with intended manufacturing use, minimizing time and cost associated with qualifying raw materials

Collaboration through the Early Access Program

New Product Selection

- Select products based on your manufacturing needs
- Suggest enhanced product specifications, format and configuration

Qualification

- Coordination of manufacturing and testing schedules
- Opportunity to provide feedback on product performance

Risk Assessment & Document Creation

- Joint review of risk factors based on:
 - Intended product use
 - Required documentation

The Diagnostic Elite Advantage

The Diagnostic Elite program provides key attributes that enable IVD manufacturers to minimize risk and increase consistency.

Assay Consistency

Enhanced support through:

- 3 Elite lots available for validation
- Identification and control of critical manufacturing and packaging processes

Quality & Regulatory Compliance

Elite offers:

- QA batch review
- Retained batch samples
- Prioritized product investigations
- Unannounced audit support
- Enhanced documentation

Quality Materials at a Competitive Price

Fit-for-use materials for IVD:

- Elite offers most GMP attributes without typical GMP costs
- Competitively priced vs. R&D grade material

Robust & Transparent Supply Chain

We serve the IVD market as a recognized partner through:

- Global distribution network that allows fast, accurate and compliant delivery
- Transparency of manufacturing site or supplier identification

Enhanced Change Control Notification

To support your risk mitigation, our change control provides:

- Increased notification timeframe
- Additional notifiable events

Change Avoidance or Reduction

Elite products require:

- Management of change
- Management of third party-supplied raw materials and finished goods



To discuss your specific product needs, please contact your representative.
Find contact information for your country at: **[SigmaAldrich.com/offices](https://www.sigmaldrich.com/offices)**
For Technical Service visit: **[SigmaAldrich.com/techservice](https://www.sigmaldrich.com/techservice)**

[SigmaAldrich.com/diagnosticelite](https://www.sigmaldrich.com/diagnosticelite)

