Critical raw materials for mitigating risk in IVD manufacturing
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.

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.

For more information, visit SigmaAldrich.com/diagnosticelite
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.

<table>
<thead>
<tr>
<th>Example Notifiable Events</th>
<th>Diagnostic Elite Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expiry or Recommended Retest Date</td>
<td>Immediate Immediate</td>
</tr>
<tr>
<td>Storage Temperature</td>
<td>Immediate Immediate</td>
</tr>
<tr>
<td>EQP Status Downgrade</td>
<td>Immediate Immediate</td>
</tr>
<tr>
<td>Product Recalls and Alerts</td>
<td>Immediate Immediate</td>
</tr>
<tr>
<td>Product Master Data (Name, formula weight, CAS#, etc.)</td>
<td>Immediate Immediate</td>
</tr>
<tr>
<td>Label Changes (CAS#, formula, storage temp, weights)</td>
<td>Immediate Immediate</td>
</tr>
</tbody>
</table>
| Vendor (company we place our PO with)        | 2 weeks 4 weeks 12 weeks  
| Country of Origin (in-house manufactured)     | 2 weeks 4 weeks 12 weeks  |
| Manufacturing Site (in-house manufactured)    | 2 weeks 4 weeks 12 weeks  |
| Analytical Release Specifications and/or Methods | 2 weeks 4 weeks 12 weeks  |
| Site - Packaging                              | 2 weeks 4 weeks 12 weeks  |
| Site - Finished Product Testing Laboratory    | 2 weeks 4 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 |

For more information, visit SigmaAldrich.com/diagnosticelite

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

For more information, visit SigmaAldrich.com/diagnosticelite
The Diagnostic Elite program provides key attributes that enable IVD manufacturers to minimize risk and increase consistency.

**The Diagnostic Elite Advantage**

**Assay Consistency**
Enhanced support through:
- 3 Elite lots available for validation
- Identification and control of critical manufacturing and packaging processes

**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

**Quality & Regulatory Compliance**
Elite offers:
- QA batch review
- Retained batch samples
- Prioritized product investigations
- Unannounced audit support
- Enhanced documentation

**Enhanced Change Control Notification**
To support your risk mitigation, our change control provides:
- Increased notification timeframe
- Additional notifiable events

**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

**Change Avoidance or Reduction**
Elite products require:
- Management of change
- Management of third party-supplied raw materials and finished goods

For more information, visit [SigmaAldrich.com/diagnosticelite](http://SigmaAldrich.com/diagnosticelite)