CATEGORY RESOURCE GUIDE

Phlebotomy

Included in this document

(Click to view each section)

Vizient award overview

Awarded suppliers

LB0931 – Becton Dickenson
LB0932 – Greiner Bio-One North America
LB0933 – HTL-Strefa
LB0934 – Kawasumi Laboratories
LB0935 – Novaplus®/Medicore
LB0936 – MediPurpose
LB0937 – Myco Medical Supplies
LB0938 – Owen Mumford USA
LB0939 – Retractable Technologies
LB0941 – Sarstedt
LB0942 – ICU Medical

Distribution

Both direct and distributed through the following distribution channels:

Medical-surgical
Laboratory

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Questions? Contact supplyassurance@vizientinc.com, pharmacyquestions@vizientinc.com, novaplus@vizientinc.com.

Making supply uncertainty a thing of the past, not the future

To help members maintain supply assurance for essential products, Vizient shares insights via **category resource guides** on vizientinc.com. These category-specific documents contain comprehensive manufacturing, logistics and utilization insights to help members source supplies with confidence. Category resource guides are one way we're building supply assurance together.

Market landscape

The phlebotomy category includes tubes, needles and lancet sub-categories. The category has experienced significant supply challenges throughout COVID-19, especially tubes. Supply disruption peaked with COVID-19 and has steadily been improving during the past year. All suppliers are now either fully recovered or expected to recover by the end of 2023. Needles were less affected with shortages due to the many different suppliers and options available. Additionally, the demand for tubes/needles/lancets has normalized post-COVID-19, which has aided in supply recovery.

Production cost inflation, labor challenges and regaining customer confidence in the ability to supply have affected this category.

The major barrier to entry into the tube market is Food and Drug Administration (FDA) clearance which is why there are only three total full-line manufacturers, as detailed below.

Supplier	Tubes	Needles	Lancets	Non-blood collection*
BD	X	X	X	X
Greiner	X	X	X	X
Sarstedt	X	X	X	
Smiths		X	X	
Myco		X		
Kawasumi		X		
RTI		X		
Owen Mumford		X	X	X
Medipurpose			X	
HTL-Strefa			X	
Novaplus/MediCore			X	

Manufacturing insights

Product overview

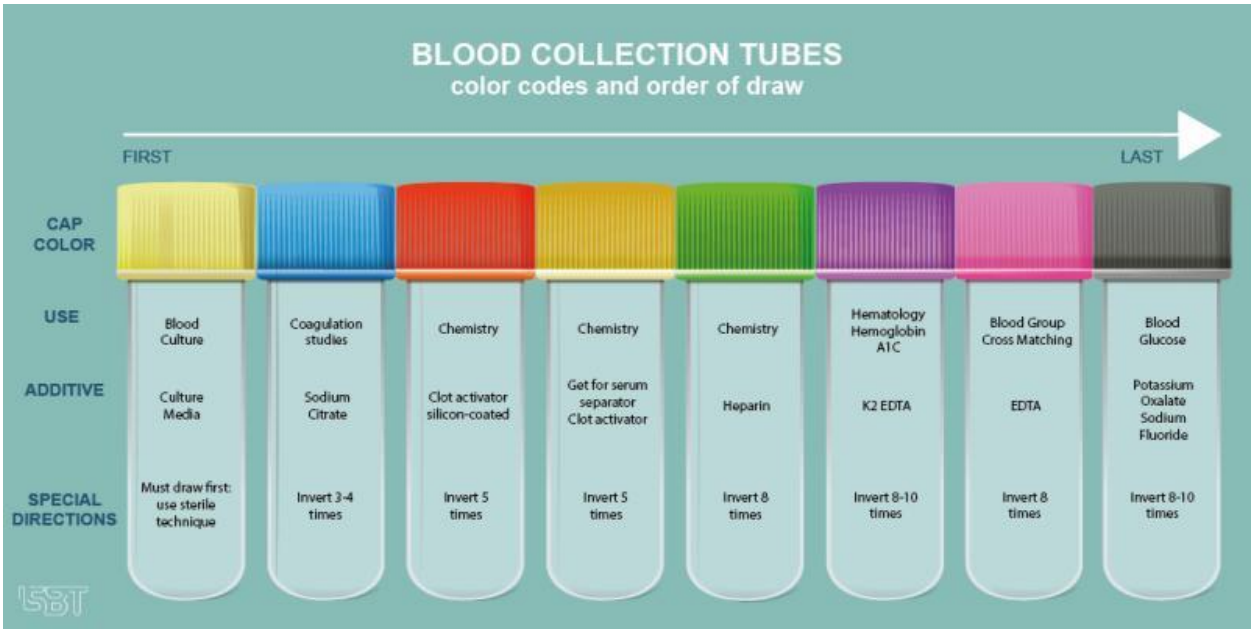
Phlebotomy is the drawing of blood (as by venipuncture) for transfusion, apheresis, diagnostic testing or experimental procedures. The products in this category can be broken into three subcategories: needles/wingsets, collection tubes and lancets/heelsticks.

Needles/wingsets

- Butterfly needles come in different gauges and with or without tubing.
- Push button needles come in different gauges and with or without tubing.
    - Key differentiators for needle selection are functionality in how the needle operates (how the needle retracts or where the button is located etc.), cost (discounts offered in relation to spend within other sub-categories) and quality which can be tied to the manufacturing process.

Collection tubes

- See the table below for top tubes used and specific uses. Plastic tubes are now the industry standard as they are lower in cost and are lighter, unbreakable and easiier to dispose of. Glass tubes are still utilized for specialty testing but are being used less and less.
- Most tubes in the market are vacuum tubes, where blood is passively drawn into the tube. A variation is Sarstedt, where a vacuum must be produced manually via a different blood-drawing procedure.



Lancets/heelsticks

- Used to collect small amounts of blood (a few drops), it is primarily used for babies and children instead of a needle. It comes in different sizes, which are differentiated by their penetration depth.

Selection factors

Choosing the most appropriate blood-sampling system is important, and outlined by the World Health Organization:

Closed systems

Safer than open systems, closed systems for blood sampling are preferable:

- Needle and syringe: Hypodermic needles and syringes are the most often used for blood sampling.
- Choice of gauge: Having the right size helps prevent damage. A needle that is too large will tear a vein, causing bleeding (hematoma). A needle that is too small can affect the test; laboratory tests requiring whole blood cells or hemoglobin and free plasma won't have valid results. A larger gauge than need for drawing blood is required for transfusion blood collection.
- Vacuum extraction systems: The risk of direct blood exposure is decreased when using closed vacuum extraction tube systems. Available in most well-resourced countries, the systems also make it easier to take multiple samples from a single venipuncture. However, not all countries may recommend the systems, which are safe but require training to use. The double-ended needles come in several recommended gauge sizes, and the ends are covered by a rubber cuff that is screwed into the barrel, which can also be referred to as the tube holder, evacuated tube needle holder or bulldog. The barrel is screwed into place via the threads that separate the two ends. The barrel also protects phlebotomists from direct blood contact while it holds the sample collection tube, which is under vacuum, in place. The tube is pressed on to the needle after it's in the vein, and the required amount of blood is automatically drawn into the sample tube via vacuum. Needle, barrel and the laboratory sample tubes (adult and pediatric) all come with the system. There are also appropriately colored tops for different types of samples. The systems also have mechanisms that ensure the needle is unavailable after its use. There are also vacuum systems that use winged butterfly needles and Luer-lock connectors. The winged butterfly needles are also available with safety-engineered devices.

Open systems

Hypodermic needle and syringes, as well as winged steel needles attached to a syringe, are available in open systems.

OEM and manufacturing location

The two main full-line suppliers, BD and Greiner, manufacture most U.S. products within the U.S. Both also have additional manufacturing capabilities abroad, including South America, Europe and Asia. Sarstedt manufactures products in Europe, as well as North and South America, and Australia.

Needle and lancet manufacturing is predominately done in Asia. Nipro out of Japan manufactures many needle offerings within the category.

For product-specific manufacturing information, contact your supplier representative.

Raw materials

The raw materials used in most blood collection tubes are predominately polyethylene terephthalate (PET). Coagulation tubes are made up of PET and polypropylene (PP).

Additionally, many tubes include various additives required for different tests. Those additives include gel, sodium citrate, lithium heparin, sodium heparin, sodium citrate and ethylenediaminetetraacetic acid (EDTA), and their use is based on tube and testing type.

The raw materials used for needles and lancets are PET, PP and stainless steel.

The lastest manufacturing insights are available here.

Regulatory and approvals

The FDA is aware the U.S. has experienced significant interruptions in the supply of several blood specimen collection (blood draw) tubes because of an increase in demand during the COVID-19 public health emergency and recent vendor supply challenges. So, the FDA has expanded the medical device shortage list to include all blood specimen collection tubes. The FDA previously issued a letter to healthcare and laboratory personnel on June 10, 2021, about a shortage of sodium citrate blood specimen collection (light blue top) tubes.

For more information, click here.

Non-awarded suppliers

All full-line (offering tubes, needles, lancets) phlebotomy suppliers have Vizient contracts. The market players for needles and lancets are wide-ranging with multiple smaller competitors not on contract.

Logistics insights

Transportation/shipping

Generally, products are shipped via ocean freight or air outside of the U.S. Within the U.S., ground freight is used.

- BD uses ocean outside of the U.S. and ground within U.S.
- Greiner ships to distribution partners via freight, for imported items from Austria and Asia; ocean freight is used for some air freight for urgent items.
- Smiths/ICU Medical uses ocean freight.

Primary ports used

- Greiner uses East Coast ports in Charleston, S.C., and Wilmington, N.C., as well as West Coast port in Los Angeles and occasionally San Diego.
- Smiths/ICU Medical uses West Coast ports at various locations.

Distribution center location

- BD – Four Oaks, N.C.; Plainfield, Ind.; Redlands, Calif.
- Greiner – Monroe, N.C.

- Sarstedt – Newton, N.C.
- Smiths/ICU Medical – Olive Branch, Miss.

See the additional freight update here.

Product storage

- Tube shelf life varies from six to 24 months, with 12 to 18 month being the average. This is dependent on the type of tube, additives used and how long the vacuum can be maintained.
- Needle/lancet shelf life typically varies from two to five years depending on the individual product and supplier.

Utilization insights

Clinical contract support resources

Supplier specific product support specialists are available.

Conservation strategies

The FDA is aware the U.S. is experiencing significant interruptions in the supply of several blood specimen collection (blood draw) tubes because of an increase in demand during the COVID-19 public health emergency and recent vendor supply challenges. The FDA is expanding the medical device shortage list to include all blood specimen collection tubes. For more information, click here.

Visit Manage Blood Collection Tube Shortage, Conservation is Key for the most up-to-date information about conservation recommendation and the importance of communication.

Because predicting the next supply shortage is impossible, it is important that healthcare providers not only adopt and implement care practice strategies to conserve critical products and supplies, but they also sustain leading practices that will help ensure the availability of essential products post recovery and in the future.

Healthcare providers and other leading organizations have identified and recommend the following actions:

- Assess and identify all hospital services.
- Identify and list critical products, supplies, and resources required to sustain operation of those areas identified and ranked in the first step.
- Maintain the internal planning team document with accurate information. Review and update the document on a routine basis with current employee contact information. If a team member no longer works in the organization, identify the replacement and communicate the information to all stakeholders.
- Communicate practice changes and procedures frequently to staff and stakeholders.
- Hold regularly scheduled planning meetings in the absence of a supply chain shortage or event. This will help to ensure that identified processes and protocols remain relevant and any issues requiring revisions and/or updates are addressed in advance of a shortage or disaster.

If your organization has implemented conservation strategies for this product category, or any other category, please share your information here. The information you share will be anonymous unless you grant Vizient permission to share.

Supply chain programs

Diversity

Myco Medical Systems (LB0937) are Vizient diversity suppliers. Vizient's Supplier Diversity Program supports the development of minority-, woman-, disability-, LGBT- and veteran-owned business enterprises that meet high-quality standards. We also strive to work with suppliers who proactively seek strategic partnerships with diverse companies. For more information, click here.

Novaplus

Medicore (LB0935) is a Vizient Novaplus supplier. Through Novaplus, access to products goes deep with more than 15,000 individual line items – including numerous high-demand items. The brand encompasses a broad range of categories needed across the care continuum, such as anesthesia, business products and services, diagnostic imaging, food, laboratory, medical, orthopedic, pediatric, pharmacy, respiratory and surgical. Today as the capabilities, expertise and purchasing power of Vizient grow, we offer expanded value so you unlock even more from your private-label purchasing. For more information, click here.

Planning for disruptions

Best practice strategies

Vizient offers the following best practices to help members manage disruptions. These suggestions are available to help you gain insight on how the industry is managing supply challenges.

If your inventory is low

Vizient is committed to bringing hospitals, manufacturers, distributors and the industry together to talk about this issue and any long-term implications. We feel continued dialogue about the issue by experts from hospitals, manufacturers, distributors and industry will be crucial to ultimately arriving at a solution to the vexing issue. During critical supply periods, members should continue to order their normal levels of products in order to ensure continued availability for all institutions.

If you begin to experience a shortage:

- Evaluate your current supply.
- Contact your local supplier representative and report exactly how many days' supply you have left.
- If you are not getting a response from suppliers, contact Vizient so we can facilitate communication between member and supplier; provide whether you are ordering direct or through distribution (med/surg or pharmacy), and indicate supplier and distributor (if applicable) when you contact Vizient.
- We encourage you to continue the conversation within your organization, with your peers and with the manufacturers and distributors to identify ways to manage.
- Submit inquiries to disasterresponse@vizientinc.com.

Expedite supply resolution

To expedite resolution for supply issues, contact your local supplier and provide the following information:

- The description and item number of the product that is experiencing a shortage
- Whether you are purchasing directly or through an Authorized Distributor
- Days' supply remaining in your inventory

If expanding your facility

We suggest members notify suppliers when expanding their facilities to assist in planning and anticipate increases in allocations. You should consider notifying your suppliers at least three months ahead of the completion of your facility to ensure sufficient capacity.

Building supply assurance together

Collaboration among suppliers, distributors, members and Vizient strengthens the assurance of supply for all stakeholders. Our wealth of experience, actionable data and predictive planning helps to strengthen supply assurance. Further, our work with stakeholders focuses on improving supply chain risk mitigation as we collaborate to enhance data, increase supply visibility and expand inventory access.

Four themes keep us centered and are the pillars of our supply chain assurance efforts: insights, access, enablement and advocacy. Learn more about our supply assurance strategy.

In the event of a supply disruption, Vizient will publish a product disruption brief to the Supply Assurance webpage. Curated by Vizient experts, these documents provide a summary of current conditions and strategies to manage product-level disruptions.

In addition to our disruption briefs, Vizient also compiles all known disruptions into the monthly Supply Update Executive Summary which tracks all supply chain disruptors, including current market challenges, category-specific product updates and recovering markets.

Whether a supply disruption is the result of a natural or human-made disaster, it is imperative that members are informed. The Vizient Disaster Preparedness webpage was developed to help providers meet supply chain needs before, during and after an event. The Supply Update section of the guide is updated on a frequent and routine basis with communication from all awarded suppliers that have manufacturing facilities in areas impacted by a disaster. Additionally, a status update list of those manufacturers whose operations have been affected, as well as a list of impacted product(s), will be maintained and updated as that information is received from the supplier.

The importance of an internal planning team

Identifying an internal planning team is imperative to managing supply, mitigating risks and sustaining operations during a supply shortage. According to the Supply Chain Disaster Preparedness Manual developed by the Centers for Disease Control and Prevention (CDC), internal teams should consist of representatives from supply chain, purchasing, emergency management, each clinical/care delivery area, inventory staff, receiving and distribution staff. Relative to medication and solutions, Vizient member feedback indicated the pharmacy department as an integral member to the internal team, as clinical/pharmacy practice changes may occur. Additional members may include the facilities safety manager, security, risk management, legal, marketing and communications and public relations.

A simple internal team planning document will help to identify, contact and quickly convene relevant team members. See the sample below:

Name	Title	Department/role	Phone	Email

Once an internal team is identified, additional considerations before beginning the development and implementation of a recovery plan include the following:

- The team's goals
- The responsibilities of each planning team member
- Other department/team members who may need to be involved
- Frequency of team meetings
- How the goal/mission be accomplished
- How information will be documented and communicated to the broader audience
- A current framework for success either within your facility or from a leading organization

Stakeholder communication

During supply chain product disruptions, it is vital that accurate and timely information is disseminated to internal and external stakeholders. The following actions should be considered in an effort to facilitate and ensure informed decisions:

- Designate the point person or persons who will be responsible for developing, disseminating and monitoring all communications coming from the internal planning team.
- The internal planning team should collaborate key messages/information to stakeholders such as changes in policies and/or practice changes.
- Clearly communicate the roles and responsibilities of all staff based on the agreed upon recovery plan. If there are changes to the plan at any time, timely communication of those changes will help to increase risk mitigation and minimize interruption of patient care.
- Establish communication mechanisms for information exchange. Examples include but are not limited to regularly scheduled briefings and meetings, in-services, staff trainings, live/recorded webinars, memos and emails.
- Determine the frequency of reminders and updates regarding supply disruption status and anticipated resolution.
- Frequent updates and reminders after a supply disruption has been mitigated or eliminated help ensure ongoing success and sustainability of best practices.

Supply management and logistics

A leading practice identified in managing recent shortages is a centralized management approach of impacted product codes. A key responsibility of the internal planning group is to identify all affected product codes and to determine the amount of supply on hand, expected and any allocation protocols implemented by the supply source. Once the current product status is determined, the following actions are recommended:

- Update and maintain an accurate inventory list. Each care area that utilizes any product code on the inventory list should identify a point person to collect on hand and usage levels on an agreed upon frequency. That information should be reported back to the internal planning team. Inventory can either be managed by care delivery areas or in a centralized manner.
- Identify space in the facility to store, manage and distribute product. Designate authorized personnel responsible for maintaining the inventory (expiration dates temperature, ventilation, utilization, equipment maintenance and repair, etc.).
- Develop and seek approval for the inventory management protocol and communicate this information to all stakeholders.
- Update and maintain accurate purchase order and allocation protocols from the contracted supplier and your group purchasing organization (GPO).
- Update and maintain accurate emergency contact information for all suppliers as well as internal stakeholders. This process should be done at least every six months.

- Review the inventory management status on an agreed upon frequency with the internal planning group. Assess for barriers to its effectiveness, implement any changes necessary and communicate those changes to all stakeholders.

Planning for all levels of care and ancillary products

Feedback from lessons learned indicated the need to include all levels of care and ancillary products, if applicable, in the conservation plan. If your provider system has children's hospitals, ambulatory surgery centers, outpatient clinics and/or long-term care facilities, utilization and logistics of products and supplies must be incorporated into the plan. Additionally, it is vital that ancillary products are considered when contemplating allocations and purchase orders. During the recent drugs and solutions shortages, as large volume solution bags went on back order, smaller volume bags, compounding products and syringes also went on back order because of practice changes. Therefore, conservation planning should include actual and the additional ancillary products that may be required to sustain a clinical and/or operational practice change

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