# Lab Testing FAQs

**What activities currently take place at the Walpole facility?**
The Siemens Healthineers Walpole facility is a key R&D and manufacturing facility for our laboratory diagnostics assays for the ADVIA® Centaur suite of immunoassay instruments, the RAPIDPoint and RAPIDLab blood gas testing instruments and also the consumables for the VERSANT kPCR molecular instrument. The facility also will manufacture assays to run on the immunoassay module of the Atellica™ Solution, which is not yet commercially available. (The components of the Atellica™ Solution, including the sample handler and the clinical chemistry and immunoassay analyzers are manufactured in Flanders, New Jersey, USA.)

**What is laboratory diagnostics?**
Laboratory diagnostics is another term for clinical lab testing (also known as in vitro diagnostics or IVD), which is conducted on patient samples to, among other things, help detect or rule out diseases. The specific tests, or assays, are usually performed by clinical laboratory scientists—staff who operate the laboratory equipment.

**What is an assay/reagent?**
An assay (reagent) is a chemical and/or biological substance used in a reaction with a patient sample to detect, measure, examine or produce other substances.

**What types of laboratory testing exist?**
Clinical labs are usually comprised of several specialized sections corresponding to various scientific disciplines. The general disciplines of IVD are:

| Type of Testing | Description | Application |
|---|---|---|
| **Clinical chemistry** | Clinical chemistry tests analyze the chemical composition of blood and other body fluids, such as urine. Among the biochemical or metabolic substances measured are lipids, enzymes, hormones, electrolytes and proteins. Clinical chemistry is also used to detect drugs of abuse and monitor therapeutic drug levels. | Any deviation from the normal range may indicate disease or compromised vital functions. For example, elevated creatinine is a sign of reduced kidney function, while elevated cholesterol may indicate an increased risk for heart disease. |
| **Immunochemistry** | Immunochemistry deals with chemical aspects of immunology, or the immune system. An immunoassay is a laboratory test used to detect and quantify biochemical substances in body fluids, such as specific disease markers, hormones, viruses or bacteria. | Immunoassays are highly sensitive and assist physicians in confirming or ruling out infectious, cardiovascular and other diseases. They are important for managing disease and monitoring treatment success (e.g., cancer markers). |
| **Hematology** | Hematology testing can identify abnormalities in the blood by examining the size, shape and count of blood cells and blood cell components. | Hematology helps to detect anemia, other blood disorders and infections; to monitor immune system status; and to monitor a patient's health during treatment (e.g., chemotherapy). |

# Lab Testing FAQs

| | | |
|---|---|---|
| **Hemostasis** | Hemostasis testing is used to diagnose coagulation disorders (disorders in blood clotting). Coagulation is a response to blood vessel injury to prevent excessive bleeding. | A hemostatic analysis is usually performed before surgery and to monitor treatment with anti-coagulant medication (e.g., after a heart attack). |
| **Molecular testing** | Molecular biology deals with the structure and function of genetic material at the molecular level. The genetic information contained in DNA and RNA is unique for each organism and regulates biological development and metabolic processes. Molecular testing examines genetic material to locate specific genes that are responsible for causing a genetic disorder or belong to a virus. | Molecular testing is performed in order to confirm the presence of the virus, such as HCV, to determine the amount of virus present (viral load) and to identify the exact virus type (genotyping) to tailor treatment. |

**What is the Atellica Solution?**

The Atellica™ Solution is a flexible, scalable, automation-ready solution for laboratory diagnostics comprised of sample management, and immunoassay and chemistry analyzer components. Siemens Healthineers developed the solution based on extensive market research and a deep understanding of the needs of laboratory professionals around the world to provide laboratories greater control over sample management and analytical processes to deliver test results in a more predictable, efficient and reliable way.

The Walpole facility will manufacture assays to run on the immunoassay module of the Atellica™ Solution, which is not yet commercially available. (The components of the Atellica™ Solution, including the sample handler and the clinical chemistry and immunoassay analyzers are manufactured in Flanders, New Jersey, USA.)