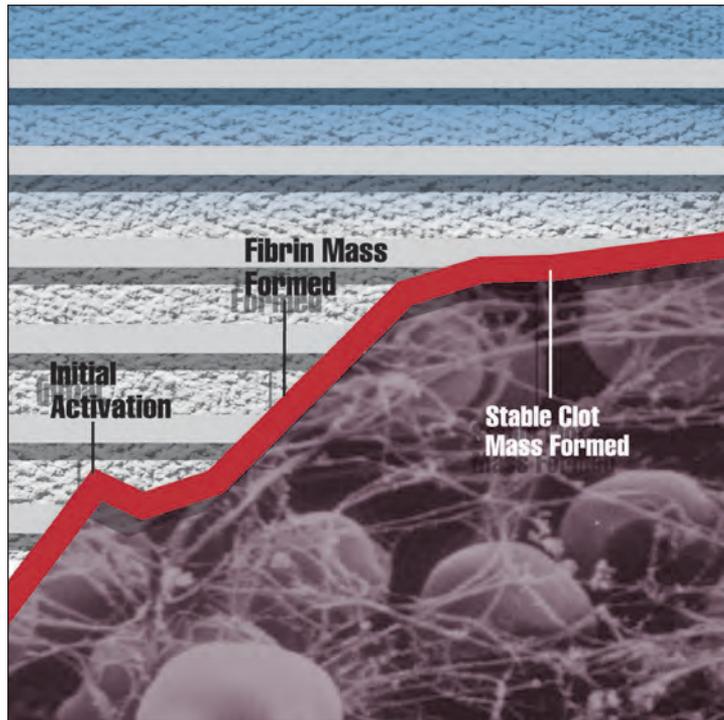


The Actalyke[®] Story...



The Actalyke® Story ... The Science

The Actalyke activated clotting time test system provides a winning combination of value-added features and cost savings. It was intended to be similar to existing ACT systems currently in use, yet with redesigned and improved components behind the faceplate to better suit today's testing expectations. In fact, there's quite a bit of science behind the improvements that were built into the system, including both the instrument and the test tubes.

Since not all of the refinements nor the science are obvious, it is noteworthy to provide an explanation of some of the key design elements and their resulting improvements. It's important to understand why Actalyke ACT test results are among the most reliable, consistent diagnostic results available today.

Actalyke Mini



Understanding the Advanced Design of the Actalyke Instrument

Both the Lee-White clotting time and manual ACT tests, which were time-consuming and highly dependent on operator technique, were eventually replaced with automated ACT methods. The Hemochron® automated ACT instrument introduced in 1969 utilized an electro-mechanical clot detection mechanism to sense the formation of a fibrin clot. This same clot detection principle is still used today. It consists of a magnet within a test tube and a magnetic detector located within the instrument's test well (positioned at 0 degrees). When a test tube is inserted into the well, the magnet detector senses the magnet within the test tube as the tube slowly rotates (figure 1).

When the clot begins to form, it causes the magnet to lift within the tube. Once the magnet has been displaced (reaching a point approximately 90 degrees from its normal position), it is no longer sensed by the instrument's magnet detector (figure 2). The instrument then gives an audible beep and displays the coagulation time.

A potential limitation to such a "single-point" clot detection mechanism (one in which a single trigger point is used to signify the clotting endpoint) is the fragility of a highly heparinized sample. Despite the procoagulant reagents used in the ACT test tubes (i.e., celite, kaolin, etc.), heparin prevents a stable

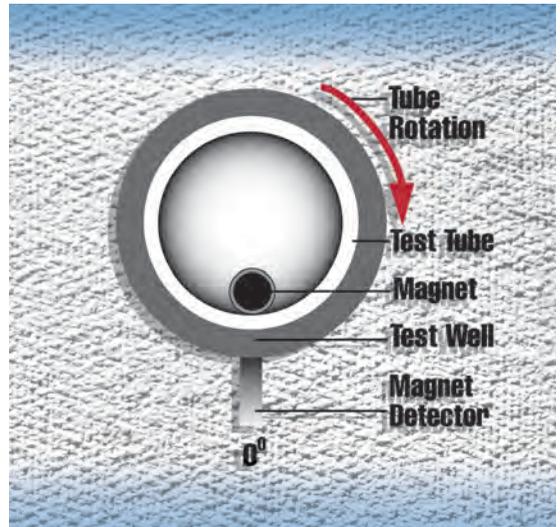


figure 1 – Single-point clot detection mechanism with magnet detector at 0 degrees

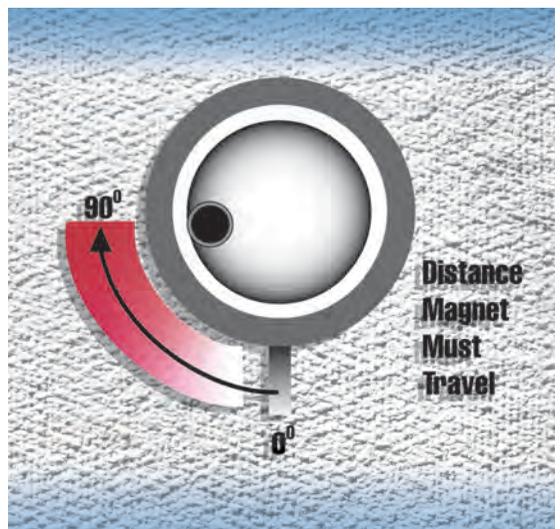


figure 2 – Distance magnet must travel to reach 90 degrees detection point in single-point clot detection system

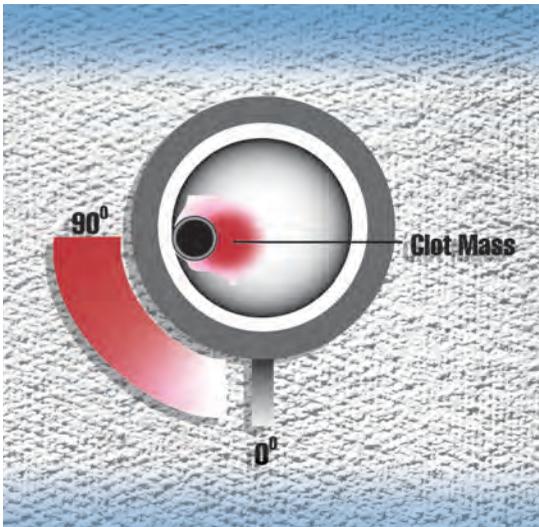


figure 3 – Rotation of the clot mass/magnet towards the 90 degree detection point

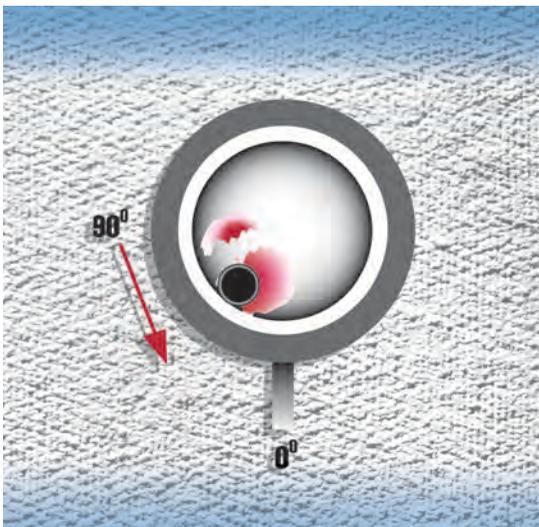


figure 4 – Gravitational pull on the unstable clot mass prior to endpoint detection

clot mass from forming for some prolonged period of time. As the clot does begin to form, the fibrin strands must be strong enough to displace the magnet approximately 90 degrees from its original position in the bottom of the test tube. In fact, the clot mass must have sufficient strength and stability to bear its own weight and rotate the necessary distance away from the single magnet detector (figure 3).

As this begins to happen, gravity puts stress on the fragile mass. If the clot is not “strong” enough, the fragile fibrin strands may break and the magnet may slide back down to the bottom of the tube where the gravitational force on the mass is the lowest (figure 4). This may occur repeatedly until the clot becomes more stable.

Until the clot can bear its own weight and reach the 90 degree detection point, the detector will not signify test completion. Thus, even though a clot may have formed, a single point clot detection method may not trigger until the clot is more stable. The clinical implications of this phenomenon when testing highly heparinized, diluted samples could be inaccurate ACT test results, poor reproducibility, or tests that “time out” due to the nature of a single -point clot detection mechanism.

To avoid this circumstance, a different electromechanical clot detection approach was designed and incorporated into the Actalyke instrument. This new endpoint detection mechanism utilizes a two-point sensor that tracks the position of the magnet from two independent locations, one at 0 degrees and one at 90 degrees (figure 5).

As the clot forms, the magnet begins to travel away from detector 1 and towards detector 2; when the magnet reaches a fixed distance between detector 1 and detector 2 (approximately 46 degrees away from detector 1, or 1 degree closer to detector 2 than detector 1), the detectors in tandem signify an endpoint (figure 6). Thus, the clot mass only has to bear its weight and travel about half the distance (46 degrees) to trigger the two-point clot detection mechanism as compared to the single-point (90 degrees).

By using a two-point clot detection mechanism, Actalyke determines the presence of a clot at early fibrin formation and is less affected by clot stability in signifying test completion. This advancement in clot detection capability can be readily noticed in the clinical setting through test result reliability. Especially on highly heparinized and diluted samples, the Actalyke system is less affected by the difficulties of detecting unstable or weak clot masses due to its two-point clot detection approach.

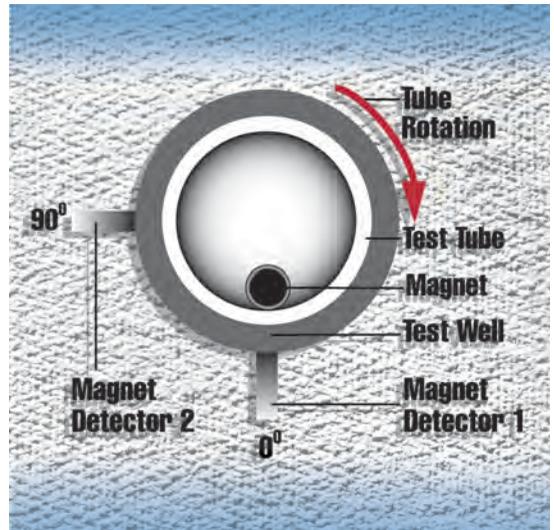


figure 5 – Two point clot detection mechanism with magnet detectors at 0 and 90 degrees

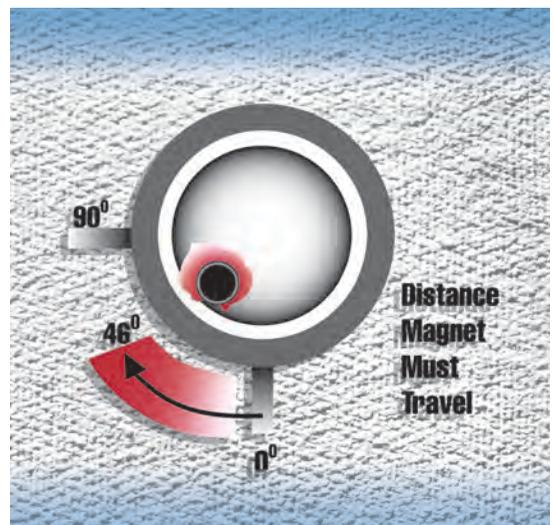


figure 6 – Distance clot mass/magnet must travel to reach 46 degree detection point in two-point clot detection system

Understanding the Advanced Design of the Actalyke Test Tube

Improving the clot detection mechanism of the Actalyke instrument was an obvious advancement over single-point clot detection principles. The science behind the test tube technology was also refined—from design to packaging—to ensure a high degree of test result reliability and consistency.

The premise of the ACT test tube seems relatively simple: place an activator in the tube, add the blood sample, and wait for the clot to form. In actuality, though, getting the clot to form within a certain timeframe, location, and strength is not as rudimentary.

For example, many patients undergoing ACT testing are quite complex with regard to their hemostatic profile. Most are moderately or highly anticoagulated with heparin, many are hemodiluted, and others receive concomitant anti-fibrinolytics, volume expanders, anti-platelet compounds, and other pharmaceuticals. These factors can have a significant effect on the ability to form a clot in the ACT tube, as well as the rate at which the clot will form, the amount of fibrin generated, and the stability or strength of the clot once it ultimately forms.

These complexities were taken into consideration in the development of the Actalyke test tubes. For example, the bottom of the Actalyke test tube provides a different “reaction chamber” from other ACT tubes on the market. In fact, the area in which the clot forms in the Actalyke tube is more tapered at the base as compared to the flatter, more square reaction chamber of other ACT tubes (*figure 7*).

This means that the Actalyke tubes provide a smaller “gap distance” between the magnet and the clot adhesion post (white plastic spindle) in the tube. Thus, the formation of fibrin strands and subsequent clot is more concentrated into a smaller area with the potential for

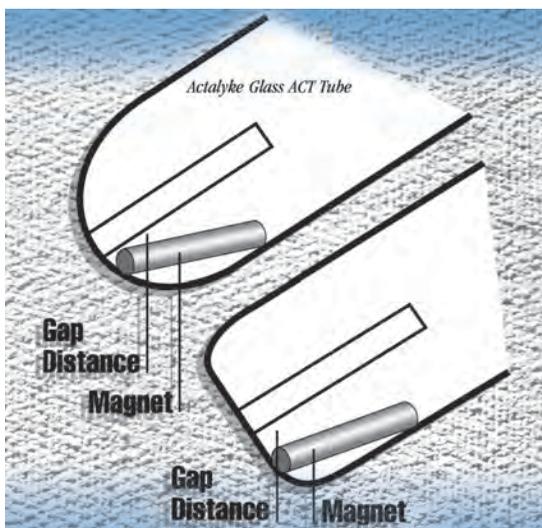


figure 7— Comparison of the gap distance in different ACT tubes

more immediate displacement of the magnet (*figure 8*). In general, it is believed that determination of the coagulation time just when the clot begins to form is the most accurate and reproducible point for measurement.

This tube design is particularly important when testing highly heparinized samples in which fibrin formation is a prolonged process. Further, these clots may be too weak to bind the magnet to the post if they are not in close enough proximity.

Ultimately, a smaller clot mass and earlier detection of the clot in its formation cycle can potentially end the test cycle quicker due to the Actalyke tube design (*figure 9*). The clinical utility of detecting the first stages of clot formation as opposed to end stage clot formation may be the ability to more accurately assess coagulability and thus prevent microemboli from forming.

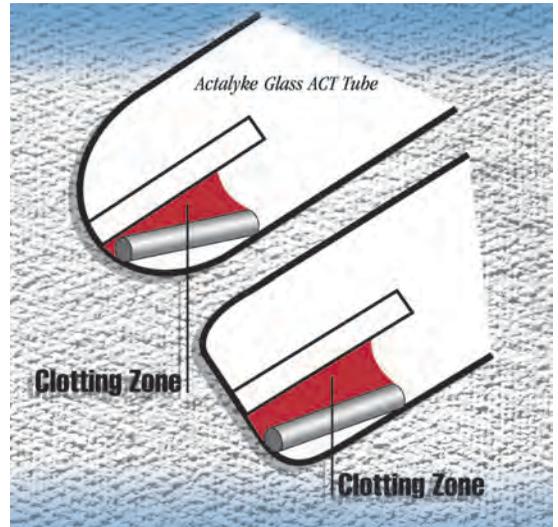


figure 8 – Comparison of the clotting zone in different ACT tubes

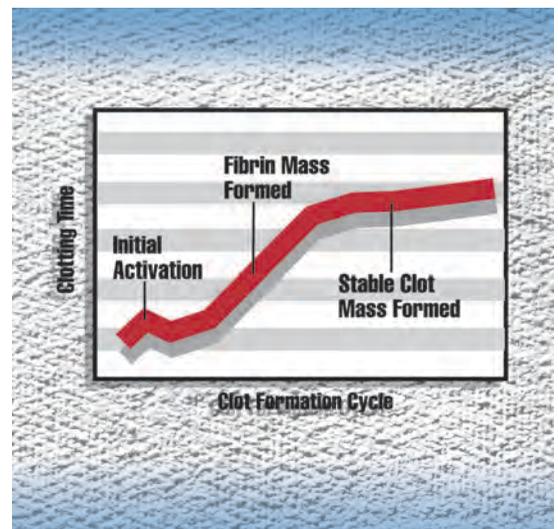


figure 9 – Clot formation cycle relative to clotting time

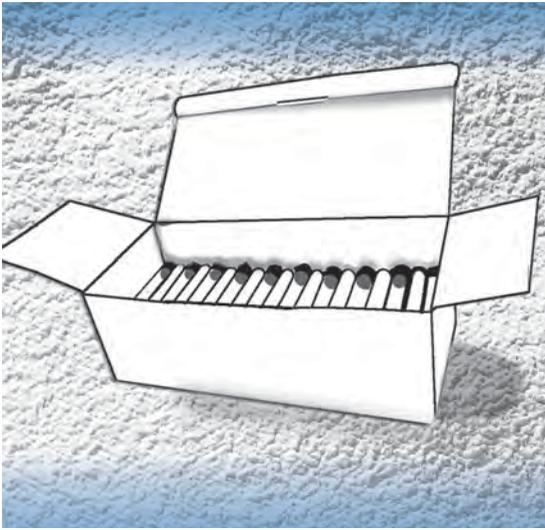


figure 10 – Tube packaging in a horizontal “head to toe” format

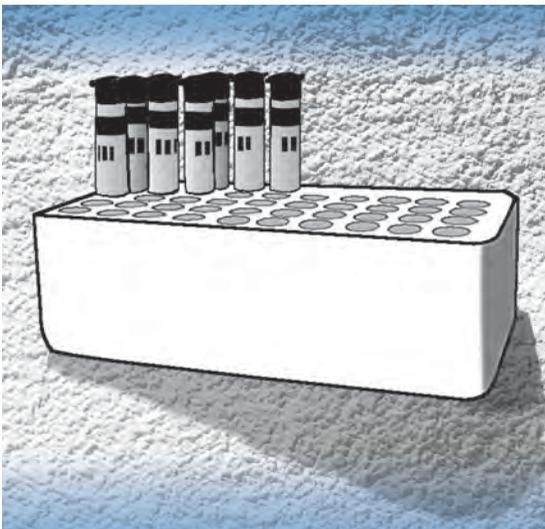


figure 11 – Tube packaging in a vertical upright format

Understanding the Advanced Packaging of Actalyke Test Tubes

During the entire test tube design process, nothing was taken for granted as status quo. Even the packaging underwent serious functional evaluation to preserve the product and enhance performance. One such consideration was to maintain the reagent in its natural powder state, and another was to localize the reagent to the reaction chamber as much as possible.

As a result, packaging of the tubes in a horizontal “head to toe” format was rejected since this approach tends to pack the reagent powder into a cake due to the steamroller effect of the magnet during shipment and storage. This caked reagent may activate the patient sample in a less consistent manner than would a loose, non-compacted powder. The “head to toe” format (figure 10) also allows the reagent to migrate out of the bottom of the tube (reaction chamber), along the entire length of the tube wall and even under the cap. Although agitation of the blood sample should be sufficient to restore the reagent into the tube’s reaction chamber, there still exists a potential for variability in the amount of reagent available to activate the clotting process.

Rather than horizontal storage, Actalyke tubes are packaged standing upright in a tube rack (*figure 11*). This vertical packaging minimizes the compression of the powdered reagent by the magnet, and it also reduces the dislodging of reagent out of the reaction chamber. Of note, the domestic market leader in laboratory blood collection tubes recently switched from horizontal tube packaging to an upright tube package. Clear benefits in reduced tube breakage and possibly in improved test performance and reliability should be realized from the Actalyke packaging design.

And there's more...

While the Actalyke instrument and test tubes build on the operation and user interface of existing ACT systems, they do not stop there. User features previously unavailable on ACT systems such as a barcode reader, individually labelled test tubes, programmable set up options, and more are important upgrades to ACT technology. However, behind the scenes is a new degree of science that also serves to advance ACT testing forward. Some of the Actalyke advancements may not be as readily apparent as others until more rigorous scrutiny is undertaken, yet they may be even more powerful. Whether using the complete Actalyke test tube and instrument system or its separate components, the user should enjoy clear benefits. By performing tests on the most hemostatically complex patients, the Actalyke system should demonstrate improvements in delivering clinically relevant information and in providing confidence in the accuracy of heparin monitoring.

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