

Original vs. Spurious Reagents for Hematology Analyzers – By HORIBA Medical

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Abstract

When you can't prescribe spurious medicines to your patient, why spurious reagents to Blood Analyzer? Should doctor prescribe spurious medicines to his patient? Have you ever used duplicate fuel in your personal vehicle? Do you allow your child to go for local soft drink instead of Coke or Pepsi? And last but not the least;Koolgatecannot replace Colgate for your dental hygiene, just to save few dollars and compromise on quality of your personal life? We all will unanimously agree without exception considering level of education or profession. Under similar considerations and intentions, this also applies while talking about blood testing instruments.The consequences are long-lasting and severe because it's not just vehicle, single patient or personal dental hygiene but about the entire population getting served by the results of that blood testing analyzer. All reports will guide umpteen number of surgeries and treatment protocols based on the report it generate after consuming reagents used in its system. The quality of reagentsdecides the accuracy and reliability of results for clinical decision making. In turn, accuracy and reliability of results will decide the success of treatment or surgery or avoiding unnecessary medicine prescription.

INTRODUCTION

What are Original Reagents?

Those chemical reagents that are ready beneath strictly controlled standardized conditions of temperature and pressure, utilizing uncontaminated ingredients with commonplace preparations, and registered by approved bodies or vendors following internationally acceptable commonplace GMP procedures is taken into account as a creative chemical agent.

What are Spurious or Duplicate Reagents?

Those chemical reagents or solutions ready beneath varied and non-standard conditions of temperature and pressure, applying sub-standard and contaminated ingredients procured from non-registered sources or vendors while not following any commonplace GMP norms could also be thought-about as a spurious or duplicate chemical agent. They're usually used as a substitute to avoid wasting price.

Research by engineers from IVD companies has unearthed clearly that most of the break-downs and malfunctionality of instruments are found in those laboratory set ups which use spurious or locally manufactured duplicate reagents to operate their hematology analyzers. Main reasons informed by the laboratory owners are economic ease, supply issues, workload, non-availability of original reagents or lack of manufacturing facility with the instrument manufacturer. Any factor may be considered but the effect remains doubtful and unreliable results, poor treatment decisions and outcomes including implications on the instruments performance and utility life.

What are thefactors promoting usage of duplicate reagents?

Cost Saving

Cost is one in every of the foremost normally cited reason by laboratory workers for using substandard or duplicate

reagents for his or her instruments. But considering future implications these reagents negatively have an effect on the accuracy & exactness of the instrument. It conjointly shortens the operational lifetime of the instrument while not even showing any visible symptomatic changes directly evident in a very short run. Compromising on quality by saving the price isn't a rational alternative for any SOP driven laboratory involved regarding their patient's health.

Easy Supply

Local vendors are well versed with the transportation and easily arrange for best logistics as per customer ease, thus also one of the reasons for choosing spurious reagents by the laboratories. Although not convincing, this reason somewhere needs to be looked upon by the IVD companies manufacturing the hematology analyzers that reagents are available round-the-clock and strategic logistic arrangements are made based on the local needs and requirement of the reagents. Manufacturer need to ensure that original reagents are made available in the territory where the installations are made on a regular basis and regular timely forecasting as per the local needs.

Laboratory Work-Load

Although superficially we tend to might say that laboratories with significant work-load want constant and simple flow of reagents otherwise to stay the work at pace, they'll choose the native reagents. However, it are often simply analyzed that for those laboratories wherever work-load is significant wants higher and additional acutely aware usage of reagents. As these laboratories area unit additional liable to get their analyzers giving wrong results or contamination likelihood is that a lot of higher in these laboratories. These laboratories also are additional liable to human errors which may additional complicate the matter, once it involves

patient health outcomes. Thus, it's suggested that these laboratories should make sure that they're mistreatment original and producing company primarily based reagents to bring the suitable quality in their report.

Lack of Manufacturing Facility with Analyzer Company

Most of the businesses particularly within the country like India are the used distributors of the haematology analyzers. This additional complicates the matter and creates a lot of serious concern to the matter of spurious reagents. As these instruments are factory-made on OEM basis and therefore the distributing company has no complete information concerning the impact of spurious reagents. Simply to extend the sale, they never keep their customers wise concerning the negative outcomes of using duplicate reagents factory-made domestically. Instrument factory-made in China beneath the assumptions supported Chinese atmosphere and culture however the reagents are created by Indian native makers supported the Indian scenario and economic standards. This contaminates the complete market not simply in terms of price however impacts the general perception of the client concerning the performance of the analyzers out there within the Indian market.

This is one in every of the important factors to be thought-about by any medical laboratory owner that they need to opt for the haematology instrument a lot of or less from the corporate that not solely has sensible range of installations however additionally manufactures the instrument in-house however additionally has capability of producing reagents employed in the instrument. This not solely enhances the quality of the producing company within the market however additionally helps in winning the confidence of the pathologist.

CRITICAL ANALYSIS

How “Change in Reagent” affects “Blood Analysis” by Hematology Analyzer?

Hydraulics: Critical Balance between Engineering & Chemistry

Blood cell analysis uses one in all the universal principles of science i.e. “Hydraulics” that is incredibly sensitive to the changes in properties of liquid, liquid flow, temperature, pressure, chemistry or the other flow connected factors. It's an subject area of Engineering and chemistry. Whenever any of the 2 shows amendment, the impact on the opposite is seriously pronounced, anyhow.

Most hematology analyzers contain special equipment to take care of its fluid mechanics and therefore giving its correct and balanced functioning of all its elements. This fluid mechanics equipment consists of tube, O-rings, aperture, valves, chambers which supplies route of flow for chemical agent and sample consequently responding to any changes found in blood samples or in reagents.

Any change in the chemical properties, composition or flow properties like viscosity or surface tension of the liquid will affect its flow through the tubings, its ability to cross the aperture and ability to lyse the cells etc. These will directly or indirectly impact the overall process of cell analysis and counting by the analyzer.

MERITS OF USING ORIGINAL REAGENTS:

Strictly prepared with standard procedures and SOPs and constant and consistent composition as per the technology requirement.

1. Hydraulics of the hematology analyzer can be kept intact.
2. Minimum or negligible variation with change reagent LOT, whereas substandard preparations of reagent

may cause damaging variation due to substandard protocols and SOPs used to manufacture them in a small unlicensed set-ups built locally.

3. Better maintenance of pressure and vacuum for the O-rings & valves throughout analysis process in the system.
4. Last but not the least, original reagents keeps the warranty and accountability of the manufacturing company intact and builds mutually better and trustworthy relationship with the customer.

DRAWBACKS OR DEMERITS OF SPURIOUS REAGENTS:

Some of the baneful consequences of using duplicate reagents on your hematology analyzers are:

- Lot to Lot variation of reagent composition
- Unlicensed or Non-standard manufacturing set-up
- Non-Compliance with GMP Guidelines
- Affects Hydraulics parameters like pressure and vacuum in sample and reagent flow tubing
- Indirect Breach of Trust & Confidence with instrument manufacturer and loss of long-term support and service agreement

CONCLUSION

1. Use original Reagents manufactured/provided by the instrument manufacturing company
2. Estimate best forecasting for your laboratory to avoid forced buy from local manufacturer
3. Do not compromise quality for cost on reagents
4. Maintain trustworthy relationship with your instrument manufacturer
5. Last but not least, get registered on www.habx.in to know more about hematology important issues and concerns