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Short Communication.

Water Quality In Medical Laboratories

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ABSTRACT

Water quality is an important factor affecting the quality of test result in laboratories worldwide. However, till now, water quality control is neglected in most of the medical laboratories. In this short communication, we have discussed the importance of maintaining proper water quality in diagnostic laboratories.

Water Quality In Medical Laboratories

Water quality has always been a very important aspect in ensuring the performance of a medical laboratory.Howeversadlyit is also one of the most neglected or better to say overlooked parameter in day to day quality monitoring in a diagnosticsetup.

Requirement of Clinical grade water in a Laboratory

Clinical grade water is basically required for following purposes in a medical laboratory:

1. Automated analyzersfeed
2. High end manual assays like PCR, Next generation sequencing (NGS),HPLC, Liquid chromatography tandem mass spectrometry (LC-MS/MS) based assays
3. Reagent reconstitution, Sample dilution forassay purpose
4. Others like buffer preparation, blank and standard solutions, culture media etc.

The autoanalyzers require high quality water for various purposes, encompassing almost all steps of sample processing as well as pre or post analysis laundry of different parts of analyzers including cuvette wash station, sample and reagent probes, instrument pipettes, internal tank (reservoir) and incubator baths in photometers. High purity water is also required for overall health of the analyzers to ensure robust, optimal and uninterruptedfunctioning.

Impact of poor quality water in a laboratory

Poor quality water may lead to complete system failure in a medical laboratory either in the form of breakdown of the analyzers or run failure in ongoing assays.According to Clinical Laboratory Reagent Water (CLRW) specifications, there may be 4 key types of impurities in pure water namely ions, particulates, organics and bacteria (including bacterial by-products)[1]. Notably, bacteria and ions have an impact across the widest range of applications be it general chemistry, enzyme analysis, molecular testing, EIA or toxicology.Analyzers with ion selective electrodes, analyzersrunning on colorimetric principles, modern days' immunoassay analyzers and high end analyzers like Next generation sequencer (NGS), LC-MS/MS not only demand high purity water but also consistent and uninterrupted supply in many cases.Water impurity in the form of ions, particulates, organics and bacteria may lead to cuvette contamination, sample/reagent probe contamination, errors in sample and reagent dilution, poor reagent stability, level sensing error, reduced calibration stability and sensitivity, capillary blocking, scaling and many more. Regarding assays, routine biochemistry assays like calcium, alkaline phosphatase, LDH, amylase, iron, creatinine kinase etc., HPCL based assays, ion exchange chromatography, polymerase chain reaction, heavy metal testing need high purity water without which quality and reliability of these assays are considerably compromised.Molecular diagnostics requires type I nuclease-free water suitable for gene sequencing. Presence of DNase and RNase in water can have a significant impact on genetic analyses rendering characterization difficult or even not possible at all. To avoid interferences, this must be kept free from calcium, magnesium, organics, endotoxin and bacterial nucleases using further purification technologies, such as multiple ion exchange, dual wavelength photo-oxidation and ultrafiltration. Chromatographic techniques, for example, LC-MS/MS, GC-MS and HPLC in toxicology, require type I water with the lowest possible levels of organic contamination, best achieved by optimal system design with high purity components and dual wavelength photo-oxidation. ICP-MS and ultra-trace IC require water that is virtually free of elemental and ionic impurities, needing a high purity water system with multistage removal of ions using the highest efficiency and purity ion-exchange resins. All these ultimately lead to increased downtime, unforeseen expenditure in the long run, overdue, erroneous reports, potential misdiagnosis, delay in treatment and poor customer satisfaction affecting business as well as reputation of the lab. At the same time, such situation adversely affects laboratory's cost per test by increasing consumption of reagents due to increased need for re-assays.

Clinical grade water

The primary reference for the use of water in the clinical laboratory is the National Committee for Clinical Laboratory Standards (NCCLS) guideline, "Preparation and Testing of Reagent Water in the Clinical Laboratory," ed 3 (document C3-A3, October 1997)[2]. The NCCLS recommends that, water meet specific levels of purity for ionic content (resistivity), bacterial content, pH, and silica concentration. Additionally, the NCCLS indicates that, specific purification technologies be used to control particles and organic contaminants. The water purity is divided into ranges called "types".Type I water is

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considered ideal for procedures that, are highly sensitive to contamination, such as enzymatic assays, trace analysis and tests involving nucleic acids. These test methods demand minimum interference and maximum precision and accuracy. Type II water is required in the general laboratory for analytical procedures where freedom from organic impurities is of more significance. Type III water is used in washing of glassware, preliminary rinsing of glassware and feed water for production of higher grade water.

The NCCLS is now known as Clinical and Laboratory Standards Institute (CLSI) and subsequently the above mentioned gradation or types of water has been replaced with the with the terms Clinical Laboratory Reagent Water (CLRW), Special Reagent Water (SRW) and Instrument Feed Water (IFW). CLRW can replace types I and II water for most applications. IFW meets the type-III requirements from the previous NCCLS classification. SRW may be specified when CLRW purity is unsatisfactory or inadequate and additional parameters are required to ensure optimal water quality necessary for high end applications like HPLC, LC-MS/MS or Molecular testing.

The College of American Pathologists (CAP), a global accreditation agency has also endorsed and reinforced the CLRW and CLSI sets recognised standards.CAP recommends that laboratory water should meet the CLSI, Clinical Laboratory Reagent Water (CLRW) grade standard as a minimum.

Laboratory water purification technologies

To achieve the required purity or standard of water specified by CLRW, various water purification technologies are being used by lab water purification systems in modern medical laboratories. Prefiltration, activated carbon, reverse osmosis, electrodeionisation, deionisation, UV purification are some of the most common and effective technologies used for this purpose.Most of these systems use different technologies in combination to meet the desired result. For example, reverse osmosis, ultraviolet irradiation, and ultra-microfiltration are used to remove bacteria whereas reduction of ionic content in the water may be attempted by combination of reverse osmosis, deionisation along withelectrodeionisation (EDI).Removal of DNase and RNase can be achieved by treatment of water with UV light combined with ion exchangemedia[3].

Choosing a good quality water purification system for lab:

Commercially available HPLC grade water typically supplied in bottles are often used by labs. However, when used as an eluent this can lead to poor quality result. This may be due to contamination of the water through storage. An alternative and a better solution to bottled water is using a water purification system which ensures the quality of the water throughout the process. Considering the need of high purity water in a modern, fully automated medical laboratory which demands highly reliable, constant, uninterrupted, high volumeultra-pure water supply, multi-stage water purification system has been introduced by reputed vendors. There are usually three stages in such systems. In the 1st stage, primary treatment of the feed water can be done by prefiltration, use of activated carbons, reverse osmosis, ion exchange resins or electrodeionization (EDI). Pretreatment reduces all the major types of impurities inorganic, organic, microbiological and particulate by over 95%. The better the pretreatment the higher will be the potential quality of the final ultrapure water.In the 2nd stage, this pretreated water is stored in a reservoirand finally polishing of this reserved water (3rd stage) is achieved by combination of two or three different technologies like ion exchange, carbon absorption, ultraviolet photo-oxidation, ultrafiltration andrecirculation.

Hence a pre-installation site survey, feed water quality check and understanding the requirement of type of water purification technology for the lab, good water purification system design as per requirement, evaluation of vendor especially in view of after sales service, ability of the vendor to maintain, trouble shoot promptly with minimum downtime, supply consumables and spare parts in no time whenever required, user testimonial or feedback and cost of consumables, cost of AMC (annual maintenance contract) should be kept in mind before going ahead for procurement.

Conclusion: Quality of water is of prime importance in a medical laboratory. With the growing need of high volume and complex testing, there is an increasing demand of higher purity water requirement by laboratories. Considering importance of good water purification design for reliable test results and long life of analyzers,laboratory should be careful and take utmost care during selection of its water system as it will directly impact the productivity, efficiency and accuracy of workflow in a laboratory.

Conflict of Interest

The authors declare no conflict of interest.

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