

SYSTEM FOR POINT OF CARE DIAGNOSIS AND/OR ANALYSIS

[0001] The present invention relates to a system for point of care diagnosis and/or analysis, and to a cartridge and to an apparatus thereof. Such a system could be a bench analyzer, a STAT lab or a POC diagnosis system.

[0002] Over the last years point of care diagnosis and analysis has become more and more accepted. With this technology, body fluids analysis and in particular blood analysis is performed at the patient bed side, e.g. in hospitals, outpatient centers or at home, within a few minutes without the need to send a sample of the body fluids to a central lab.

[0003] The system comprises a small cartridge having a sample receiving room or volume for receiving a sample of the body fluids to be analysed and/or diagnosed. For example a blood sample is injected into the cartridge which contains means for measuring the concentration of one or more specific components of the respective sample. In particular the measuring means comprise chemistry to detect the components, e.g. specific ions, proteins, antibodies etc, in the blood sample under test (some kind of a 'mini' lab). The cartridge further comprises electrical or optical connecting means at which an electric and/or optical value or signal is measurable correlating with the concentration of the respective components. This connecting means e.g. comprise electrodes exposed to the sample.

[0004] This cartridge will be connected to a diagnosis and/or analysis apparatus of the system measuring the respective concentration values or signals via said connecting means. For example the diagnosis and/or analysis apparatus is provided as a small analyzer (handheld or small benchtop) in which the cartridge can be inserted. This apparatus comprises means for diagnosing and/or analysing which e.g. qualify and quantify the chemical or biochemical reactions on the cartridges. The apparatus usually displays the measurement results, stores or prints them out and/or sends them to a central station or data management system.

[0005] The chemistry, process technology and measurement technique used for the above described cartridges unfortunately show large variations between manufacturing lots. To ensure high measurement reliability, accuracy and repeatability when determining the concentrations of the different substances, each manufacturing lot has to be characterised after production and lot specific calibration and characterisation data must be supplied together with the final cartridges. These calibration and characterisation data must be entered into the diagnosis and/or analysis apparatus which use these data to map the measured data to real concentration levels, i.e. the real concentration of the respective components will be determined in accordance to these data.

[0006] Different technologies are used today to transfer the calibration and characterisation data into the diagnosis and/or analysis apparatus. For example these data will be typed in as alphanumeric codes by hand, i.e. reading the codes from the cartridge package or the shipping containers and enter them into the apparatus by hand typing. This method is cheap but time consuming and very inconvenient for the medical staff. In addition it's a potential source for errors. Typing errors may lead to wrong measurement results and thus lead to critical safety problems.

[0007] It is also usual to provide a package, in which the cartridge is stored, with a barcode which will be scanned in with a barcode reader. This method requires a barcode reader as part of the apparatus. Problems may occur if the barcode on the cartridge package is illegible, e.g. not well printed, cracked, smeared, dirty etc. The user also needs to adjust the distance to the barcode reader and the scanning speed to get valid results.

[0008] Another solution prefers a memory chip, storing all required data. This memory chip will be placed into each shipping container. The chip must be plugged into the apparatus which then reads the calibration and characterisation data. This method does not allow to use more than one apparatus per shipping container, because per shipping container there is only one chip available. There exists also the danger that cartridges from different containers with different manufacturing lots may be mixed up resulting in wrong measurement results. Loosing the chip renders all the remaining cartridges of that shipping container unusable.

[0009] It is also possible to perform an individual 'wet' calibration for each shipping container. Individual calibrations for each shipping container are performed by the end user by means of measuring and correcting the measurement results from well known reference samples. This method is very inconvenient and time consuming since the user must supply 'gold standards' with adequate precision for each possible measurement. Forgetting to perform this tedious calibration will result in measurement errors.

[0010] It is therefore an object of the present invention to improve the correlation between a cartridge and cartridge specific data and/or information and to make the handling process easier. The object is solved by the independent claims. Preferred embodiments are shown by the dependent claims.

[0011] According to the invention each cartridge will be provided with storage means for storing cartridge specific data and/or information readable for the diagnosis and/or analysis apparatus. According to the invention the corresponding diagnosis and/or analysis apparatus will be provided with reading means for reading these cartridge specific data and/or information stored in the storage means of the cartridge. This diagnosis and/or analysis apparatus also will be provided with diagnosing and/or analysing means performing the measurement and/or the evaluation of the respective concentration values in accordance to the cartridge specific data and/or information. By adding permanent storage means to each individual cartridge, the cartridge itself contains all required data and/or information. The invention provides an inseparable combination between the cartridge and its specific data and/or information. It is now possible to provide mixed batches of different cartridges, i.e. cartridges of different manufacturing lots and/or of different type. Therefore the invention helps to avoid the drawbacks of all previously mentioned methods for data transfer.

[0012] Preferably the reading of the cartridge specific data and/or information will be performed automatically each time a cartridge is inserted into the apparatus. Therefore a manual interaction is no longer required. This leads to a reliable data transfer and time saving.

[0013] According to a preferred embodiment the cartridge specific data and/or information comprises at least one of the following data and/or information: