[0027] It may be an object according to an aspect of one embodiment of the invention to a QC database to receive and store QC improvement data for use in improved QC procedures.

[0028] It may be an object according to an aspect of one embodiment of the invention to provide QC improvement data for use in improved QC procedures.

[0029] It may be an object of the invention to obviate and/or mitigate one or more of the above mentioned disadvantages and/or problems associated with the prior art, and/or to achieve one or more of the aforementioned objects of the invention.

SUMMARY OF THE INVENTION

[0030] According to the invention, there is disclosed a quality control (QC) system for use with one or more biological and/or environmental diagnostic test devices, and one or more users and/or consumables. The system includes a QC data subsystem, a QC analysis subsystem, a QC improvement subsystem, and a QC database. The QC data subsystem collects, from the test devices, test QC data associated with ~~at least one of~~ the test devices, the users and the consumables, with said QC data subsystem collecting said test QC data from and associated with at least a local one of the test devices. For each respective one of the test QC data, the QC data subsystem identifies one or more corresponding QC parameters based on the test devices, the users and the consumables, such that the QC data subsystem identifies one or more corresponding device QC parameters, user QC parameters, and consumable QC parameters ~~the aforesaid at least one~~. The QC analysis subsystem performs one or more statistic and algorithmic analyses and determines when one or more of said test QC data associated with the test devices, the users and the consumables are outside said corresponding device QC parameters, user QC parameters, and consumable QC parameters, respectively~~determines when~~

~~one or more of the test QC data are outside the corresponding QC parameters~~. ~~When the one or more of the test QC data are outside the corresponding QC parameters, t~~The QC improvement subsystem generates QC improvement data (i) associated with the test devices, when said test QC data associated with the tests devices are outside the device QC parameters, (ii) associated with the users, when said test QC data associated with the users are outside the user QC parameters, and (iii) associated with the consumables, when said test QC data associated with the consumables are outside the consumable QC parameters; wherein said QC improvement data is based on said test QC data and on said statistic and algorithmic analyses~~associated with the aforesaid at least one~~. The QC database receives and stores the QC improvement data for use in improved QC procedures associated with the test devices, the users and the consumables; wherein said improved QC procedures are based on said test QC data and on said statistic and algorithmic analyses; and wherein said QC database is stored and updated onboard said local one of the test devices~~the aforesaid at least one~~.

[0060] According to an aspect of one preferred embodiment of the invention, the QC improvement data and/or the improved QC procedures may preferably, but need not necessarily, be based on one or more statistic and/or algorithmic analyses performed by the QC analysis subsystem.

[0061] According to an aspect of one preferred embodiment of the invention, the QC improvement data and/or the improved QC procedures may preferably, but need not necessarily, require training and/or certification of one or more of the users.

[0062] According to an aspect of one preferred embodiment of the invention, the QC improvement data and/or the improved QC procedures may preferably, but need not necessarily, provide for set-up and/or management of the test devices and/or the consumables.

[0063] According to an aspect of one preferred embodiment of the invention, the QC improvement data and/or the improved QC procedures may preferably, but need not necessarily, provide for workflow images to be taken by the test devices at regular intervals.

[0064] According to an aspect of one preferred embodiment of the invention, the QC improvement data and/or the improved QC procedures may preferably, but need not necessarily, provide a QC diagnostic application for use by the test devices.

[0065] According to the invention, there is also disclosed a quality control (QC) method for use with one or more biological and/or environmental diagnostic test devices, and one or more users and/or consumables. The method includes step (a) of collecting, from the test devices, test QC data associated with ~~at least one of~~ the test devices, the users and the consumables, with said test QC data being collected from and associated with at least a local one of the test devices. In step (a), for each respective one of the test QC data, one or more corresponding QC parameters are

identified based on the ~~aforesaid at least one~~ test devices, the users and the consumables, such that the QC data subsystem identifies one or more corresponding device QC parameters, user QC parameters, and consumable QC parameters. The method also includes step (b) of performing one or more statistic and algorithmic analyses and determining when one or more of said test QC data associated with the test devices, the users and the consumables are outside said corresponding device QC parameters, user QC parameters, and consumable QC parameters, respectively~~determining when one or more of the test QC data are outside the corresponding QC parameters~~. The method also includes step (c) of generating QC improvement data: (i) associated with the test devices, when said test QC data associated with the tests devices are outside the device QC parameters, (ii) associated with the users, when said test QC data associated with the users are outside the user QC parameters, and (iii) associated with the consumables, when said test QC data associated with the consumables are outside the consumable QC parameters; wherein said QC improvement data is based on said test QC data and on said statistic and algorithmic analyses~~, when the aforesaid one or more of the test QC data are outside the corresponding QC parameters, generating QC improvement data associated with the aforesaid at least one~~. The method also includes step (d) of receiving and storing, in a QC database, the QC improvement data for use in improved QC procedures associated with the ~~aforesaid at least one~~ test devices, the users and the consumables; wherein said improved QC procedures are based on said test QC data on said statistic and algorithmic analyses; and wherein said QC database is stored and updated onboard said local one of the test devices.

[0066] According to an aspect of one preferred embodiment of the invention, the QC database may preferably, but need not necessarily, be stored remotely from the test devices.

[0067] According to an aspect of one preferred embodiment of the invention, at least part of steps (a), (b) and/or (c) may preferably, but need not necessarily, be each performed remotely from the test devices.

[0068] According to an aspect of one preferred embodiment of the invention, in step (a), the test QC data may preferably, but need not necessarily, be collected from and/or associated with: a selected one of the test devices; a selected group of the test devices; and/or all of the test devices.

[0069] According to an aspect of one preferred embodiment of the invention, the QC database may preferably, but need not necessarily, be stored onboard a local one of the test devices. The test QC data may preferably, but need not necessarily, be collected from and/or associated with the aforesaid local one.

[0098] According to an aspect of one preferred embodiment of the invention, the QC improvement data in steps (c) and/or (d), and/or the improved QC procedures in step (d), may preferably but need not necessarily provide for workflow images to be taken by the test devices at regular intervals.

[0099] According to an aspect of one preferred embodiment of the invention, the QC improvement data in steps (c) and/or (d), and/or the improved QC procedures in step (d), may preferably but need not necessarily provide a QC diagnostic application for use by the test devices.

[0100] According to the invention, there is also disclosed a computer readable medium for use with one or more biological or environmental diagnostic test devices, and one or more users and/or consumables. The computer readable medium includes executable instructions which are physically stored thereon. The executable instructions, upon execution, encode one or more processors to collect, from the test devices, test quality control (QC) data associated with ~~at least one of~~ the test devices, the users and the consumables, with said test QC data being collected from and associated with at least a local one of the test devices. The executable instructions, upon execution, also encode the processors to, for each respective one of the test QC data, identify one or more corresponding QC parameters based on the ~~aforesaid at least one~~ test devices, the users and the consumables, such that the QC data subsystem identifies one or more corresponding device QC parameters, user QC parameters, and consumable QC parameters. The executable instructions, upon execution, also encode the processors to perform one or more statistic and algorithmic analyses and determine when one or more of said test QC data

associated with the test devices, the users and the consumables are outside said corresponding device QC parameters, user QC parameters, and consumable QC parameters, respectively~~determine when one or more of the test QC data are outside the corresponding QC parameters~~. The executable instructions, upon execution, also encode the processors to generate QC improvement data: (i) associated with the test devices, when said test QC data associated with the tests devices are outside the device QC parameters, (ii) associated with the users, when said test QC data associated with the users are outside the user QC parameters, and (iii) associated with the consumables, when said test QC data associated with the consumables are outside the consumable QC parameters; wherein said QC improvement data is based on said test QC data and on said statistic and algorithmic analyses~~, when the aforesaid one or more of the test QC data are outside the corresponding QC parameters, generate QC improvement data associated with the aforesaid at least one~~. The executable instructions, upon execution, also encode the processors to receive and store, in a QC database, the QC improvement data for use in improved QC procedures associated with the~~ aforesaid at least one~~ test devices, the users and the consumables; wherein said improved QC procedures are based on said test QC data and on said statistic and algorithmic analyses; and wherein said QC database is stored and updated onboard said local one of the test device.