

*Během sympozia klinické biochemie FONS 2014 byl v jeho části věnované informatice prezentován projekt pro mezinárodní kontrolu kvality „Percentiler“. Autory a odbornými garanty jsou Dr. Dietmar Stöckl a prof. Linda M Thienpont z belgické univerzity v Ghentu. Následující článek popisuje podrobněji aktuální stav projektu. Dobrou zprávou pro všechny uživatele FONS Openlims je, že mají možnost automatického napojení svých laboratoří do tohoto mezinárodního monitoringu kontroly kvality.*

*Ivan Červinka*

## The Percentiler (Patient Percentile Monitoring) – Invitation to participate

Goossens K., Thienpont L. M., Stöckl D.

<sup>1</sup>Laboratory for Analytical Chemistry, Faculty of Pharmaceutical Sciences, Ghent University, Ghent, Belgium

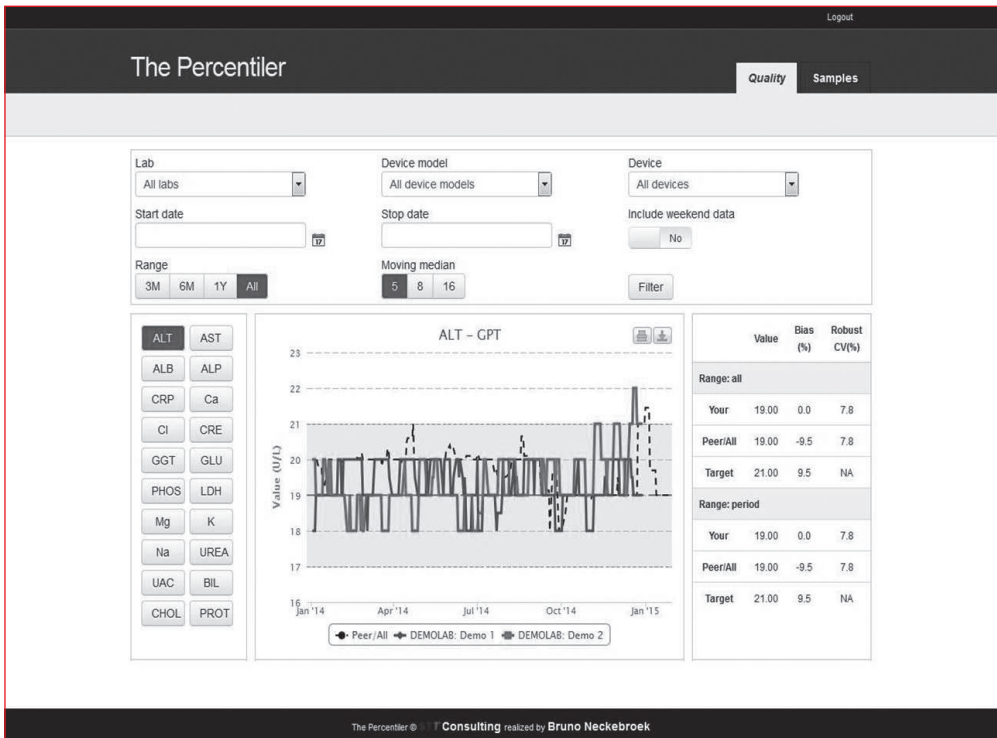
<sup>2</sup>STT-Consulting, Horebeke, Belgium

We recently developed “The Percentiler” platform which enables laboratories to keep track of their performance by using results they daily generate for patients (= Patient Percentile Monitoring). This “online” quality monitoring tool can be used to verify test stability and comparability on the basis of daily patient medians. Participation in the project is free of charge and very easy when your laboratory information system (LIS) is capable of automatic median calculation and transfer. Because of the latter, we contacted Stapro who develop and distribute the FONS Openlims. They agreed, together with the Institute of Medical Biochemistry and Laboratory Diagnostics of Charles University in Prague, to set up a pilot project for the development of automatic data sending via FONS Openlims. We are very grateful to Prof. Dr. Tomáš Zima (Dean of The First Faculty of Medicine of Charles University) and Ir. Kveta Pelinkova who were willing to serve as pilot laboratory, and also to Stapro founder Zdeněk Jirsa. Stapro also gave us the chance to present the project at the FONS 2014 Symposium of Clinical Biochemistry, Pardubice (held from 21.9. to 23.9.2014) and informed us about the progress that had been made in the development of the direct

connection of laboratories to the Percentiler via the FONS Openlims. We are very happy that this now has been finalized and that the feature is available to all users of the 5.31 version.

“The Percentiler” database is fully accessible to the project team, who investigate laboratory and peer group data for bias and trends. Critical observations are communicated in the first instance to the concerned laboratories. They are also shared with instrument vendors, and regularly, with the whole group of participants; previous reports are available at [www.stt-consulting.com](http://www.stt-consulting.com) (Empower tab). It is important to note that the identity of the participating laboratories is not disclosed to a third party under any circumstances. For on-line monitoring, the participants have a user interface (“The Percentiler”) with password access at their disposal; this tool enables them to plot the course of the moving median over time for each analyte and even individual instruments. A demo version of “The Percentiler” can be found on: <https://www.thepercentiler.be> (login: demolab, password: demo1234; see Figure 1). Investigation of data is possible on-line, however, if detailed off-line analysis is preferred, the data can be downloaded into Excel. Another functionality in the user interface allows the download of the moving median charts for each analyte. The selection possibilities further include i) n for calculation of the moving median (n = 5, 8, 16); ii) time window; iii) inclusion/exclusion of weekends. When participants report medians for two or more instruments, an instrument-specific color code is used in the charts. The assessment of the stability of laboratory testing is done against desirable bias limits from biological variation, at least for the analytes for which state-of-the-art performance allows this. However, the maximum bias limit is set to ~10%. The limits are visualized in the charts by a gray zone, and violations >1 week are considered significant.

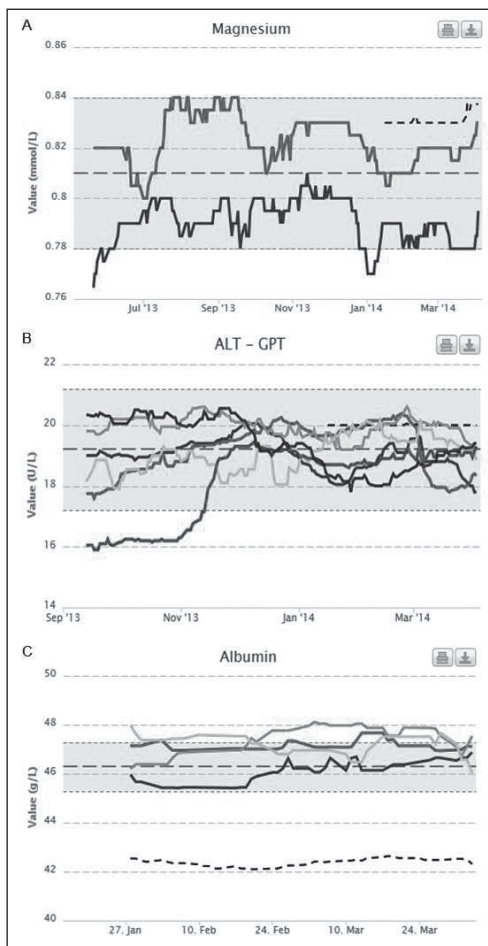
Currently (January 2015), >120 laboratories participate with ~250 instruments, distributed over the following peer groups: Advia (n = 8); Architect (19); AU (13); Cobas (154); Integra (3); Modular (10); Synchron (11); Vista (6); Vitros (26). Participation is global, however, most of the current participants come from Belgium (see Figure 2). In this stage, laboratories can monitor the performance for twenty common analytes by calculating their daily medians and sending them to the project’s database. These analytes are: albumin, alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, calcium, chloride, C-reactive protein, creatinine,



**Figure 1.** Demonstration of “The Percentiler”. The chart shows for the selected laboratory i) the moving median over the selected period (full lines); ii) the long-term median (long-broken horizontal line) and the limits used for the respective analyte (short-broken horizontal lines; the area in-between is shaded); iii) the Peer Group moving median (broken line).



**Figure 2.** Global geographic distribution of the participants in the “The Percentiler” project



**Figure 3.** Examples of observations in “The Percentiler”: (A) long-term difference between 2 instruments in a laboratory; (B) difference between instruments: 1 system is lower for a long period; (C) considerable bias of all instruments in a laboratory compared to the peer group.

$\gamma$ -glutamyl transferase, glucose, inorganic phosphorus, lactate dehydrogenase, magnesium, potassium, sodium, total-bilirubin, total-cholesterol, total-protein, urea, and uric acid.

At the moment, we are also developing a second on-line tool for quality monitoring, called “The Flagger”. Its goal is to demonstrate the effect of analytical shifts on so-called “surrogate” medical decisions, namely the flagging of laboratory results that exceed locally used cut-offs. This directly translates analytical quality into quality of medical decision making. “The Flagger” can be accessed at <https://www.theflagger.be> (login: demolab, pass-

word: demo1234). For a laboratory to participate in this platform, the report needs to include the daily % of results flagged as “hypo”- and “hyper”. This information is then automatically transferred to the “Flagger” platform. FONS Openlims software currently does not include this feature, but it is not excluded that it will in the future.

In conclusion, “The Percentiler” offers several short- and long-term benefits for the participating lab. Patient percentile monitoring gives the laboratory a direct, real-time quality indicator for the analyses of patient samples. It establishes evidence about mid- to long-term stability and/or variation of the instrument, calibrator, and reagent of the manufacturer. Particularly interesting is that it shows the shifts and/or drifts due to lot-to-lot inconsistency of calibrator/reagents (see examples Figure 3). This evidence is backed-up by information from other laboratories using the same assay. In case of unacceptable lot-to-lot variation, the laboratory may develop correction factors for compensation. Linking patient data with internal quality control, generally, strengthens the quality management/quality assurance system. In addition, the laboratory builds up evidence about the reasons for assay variation: own performance or manufacturer performance (for example, lot-to-lot-variation). This “empowers” the laboratory’s position in claims versus the manufacturer. “The Percentiler” also creates a tool for developing realistic quality goals and a tool for optimizing the physician/laboratory interface by more transparent communication of performance. Last but not least, by joining the project, you will be an empowered medical laboratory that is fit for future tasks, such as contribution to the development, implementation, and control of global health-care policies.

We cordially invite you to participate in this project. Additional information can be found on [www.stt-consulting.com](http://www.stt-consulting.com) (Empower tab) and in our previously published studies (1-6). To receive more information about the modalities for joining, please do not hesitate to contact us: Dietmar Stöckl ([dietmar@stt-consulting.com](mailto:dietmar@stt-consulting.com)), Linda M Thienpont ([linda.thienpont@ugent.be](mailto:linda.thienpont@ugent.be)) and Kenneth Goossens ([kenneth.goossens@ugent.be](mailto:kenneth.goossens@ugent.be)). Thanks again to all of our long-standing friends in the Czech Republic.

## References

1. Stöckl D, Thienpont LM. The combined-target approach: a way out of the proficiency testing dilemma. *Arch. Pathol. Lab. Med.* 1994;118:775-6.
2. Stepman HC, Stöckl D, Stove V, Fiers T, Couck P, Gorus F, Thienpont LM. Long-term stability of clinical laboratory data: sodium as benchmark. *Clin. Chem.* 2011;57:1616-7.

3. Van Houcke SK, Stepman HC, Thienpont LM, Fiers T, Stove V, Couck P, et al. Long-term stability of laboratory tests and practical implications for quality management. *Clin. Chem. Lab. Med.* 2013;51:1227-31.
4. Stepman HC, Tiikkainen U, Stöckl D, Vesper HW, Edwards SH, Laitinen H, Pelanti J, Thienpont LM; Participating Laboratories. Measurements for 8 common analytes in native sera identify inadequate standardization among 6 routine laboratory assays. *Clin. Chem.* 2014; 60:855-63.
5. Goossens K, Van Uytvanghe K, Thienpont L. Trueness and comparability assessment of widely used assays for 5 common enzymes and 3 electrolytes. *Clin. Chim. Acta* 2015 doi:10.1016/j.cca.2015.01.009.
6. De Grande L, Goossens K, Van Uytvanghe K, Stöckl D, Thienpont L. The Empower Project – A new way of assessing and monitoring test comparability and stability. *Clin. Chem. Lab. Med.* 2015 doi:10.1515/cclm-2014-0959.