SensUs

Early Contest Document

26 January 2018

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1. Introduction

Dear participants of SensUs 2018,

With this early contest document we want to give you an update on some technical information. This document contains important information regarding provided facilities, required preparations, assessment criteria, and several other matters which we feel may be of use to you already.

Please be aware that this is an early, shortened version of the contest document and that everything stated in this document is provisional. The final version of the contest document will be released on the 1st of March. Please let us know in the meantime if you have any questions or if we can be of any help!

The SensUs Organization

2. Plasma and vancomycin

Blood plasma

The matrix that will be used is citrate anticoagulated human blood plasma. We are in contact with the Dutch Foundation for Quality Assessment in Medical Laboratories (SKML) and the Dutch Association for Quality Assessment in Therapeutic Drug Monitoring and Clinical Toxicology (KKGT). They are willing to supply plasma to SensUs free of charge. We are now testing whether the plasma is indeed suitable for vancomycin testing. Should this prove to be the case, then you will be able to order plasma from KKGT, but you will need to pay the shipping costs. However, please note that you can perform experiments with plasma from other sources, because vancomycin should not be very sensitive to the matrix composition.

Vancomycin is very hygroscopic, so the preparation of samples with accurate vancomycin concentrations is not easy. We are presently establishing the protocol for preparation of the samples, together with SKML/KKGT. The protocol will provide an extensive explanation on how to make vancomycin samples in blood plasma. If you want to already perform experiments with vancomycin, then we suggest that you make samples in PBS buffer.

Vancomycin

As previously reported in the information package, the SensUs organization will use the following vancomycin to prepare the samples used during the competition: https://www.sigmaaldrich.com/catalog/product/sial/phr1732?lang=en&region=NL

For more information on vancomycin please consult our wiki: https://wiki.sensus.org/index.php?title=Vancomycin

3. Technical aspects during the contest

Equipment

The biosensor analyzer system (without computer) may not be larger than 0.8 m x 0.8 m x 0.5 m. Teams must bring their own accessories/equipment for the use of their biosensor, e.g. gloves, glasses, pipettes and pipette tips. Teams are fully responsible for the quality of their own accessories/equipment, e.g. calibration of pipettes.

Calibration samples

Prior to the contest, all teams receive calibration samples from the SensUs Organization (human plasma spiked with different concentrations of vancomycin), so that the biosensing systems can be calibrated. Samples are handed out with no analyte (blank) and with concentrations of vancomycin of 10 mg/L, 30 mg/L and 100 mg/L. You are able to perform four tests (20 µL per test) with each control sample.

Samples during the testing rounds

In total, every team receives 24 testing samples at 5 minute time intervals in a random order. Every vial that the teams receive contains 50 µL human blood plasma, spiked with vancomycin. Concentration results should be reported in mg/L. The concentration of vancomycin in the samples ranges between 5 mg/L and 100 mg/L; in addition, the sample series contains blank samples (0 mg/L).

Every team will have an independent data official. The official records the moment the sample is removed from the ice. The official also checks the sample volume that has been pipetted. At any given time, a team may measure only one sample; sample preloading and parallel sample

incubations are not allowed. When the assay is finished, the official makes sure the data (i.e. the sample number, dilution factor, used sample volume, start and end time, and the reported concentration value in mg/L) is entered into a web-based system. All reported data points are shown on screens, so everybody can monitor the cumulative data generated by the teams.

Test Results

On the public screens, amongst others the following information will be shown: the total number of reported data points, the correlation scatter plot (reported concentrations versus concentrations determined by a reference method), and histograms of the time-to-result, the sample volume used, and the dilution factor.

If a biosensor does not work or breaks down, inform the SensUs organization right away, so we can try to help to solve the problem. At any time a team can decide to withdraw from the testing rounds, discussions with the jury at the team table and posters can still take place. In case of device failure a team will still be judged on the way their sensing system was built, and on how it was supposed to function.

Safety

A few weeks before the contest, the SensUs organization will ask the teams for a list of safety measures that need to be taken regarding their biosensing system. This is to ensure safety for the public. It is mandatory for all teams to provide this information in order to participate in the contest.

4. Assessment criteria

During the contest of SensUs 2018, a total of eight awards will be given by the jury, distributed over four award categories, i.e. translational potential, analytical performance, creativity and public inspiration. Per award category, two prizes will be awarded: one to the winner and one to the runner-up. Each award category is independent, i.e. a single team can win more than one award spread over different award categories. This document contains information of the analytical performance and creativity award, information on the other two awards will follow in the final contest document.

The jury will base their judgements on the information that the teams provide via the Team Results Document and on the results, posters, presentations and discussions during the contest days.

Analytical Performance Award

The Analytical Performance award expresses appreciation for the best measurements of vancomycin in blood plasma The performance is calculated via an algorithm, which takes the following parameters into account:

- **Accuracy and precision**
  The test results should be analytically accurate. This is implemented by checking if reported data fall within a predefined accuracy bandwidth of 100%. Data outside the accuracy bandwidth of ±100% are deemed invalid.

- **Speed**
  During the contest, each team receives a blood plasma sample every 5 minutes. Also, 5 minutes is the maximum time-to-result allowed. Measurements that take longer than 5 minutes are deemed invalid. The time-to-result is measured from the moment when a sample is out of the ice to the moment the concentration value is received by the data official. The samples have to be measured in the same order as they are received.

- **Sample handling outside the cartridge (dilution)**
  Ideally a near-patient test involves no sample preparation outside the cartridge, i.e. a sample is immediately applied to the cartridge. For practical reasons, it is allowed during the contest to add reagents to the plasma sample prior to insertion into the cartridge. However, we want to stimulate teams to dilute as little as possible. The maximum allowed dilution ratio is a factor 10. Measurements generated with a higher dilution ratio will be deemed invalid.

- **Sample volume**
  The used sample volume should be as low as possible. The maximum sample volume per test is 20 µL. Measurements made using a larger volume will be deemed invalid.

The parameters detailed above will be combined in an algorithm. First a score for each *valid* measurement will be determined based on the formula below (valid meaning a measurement done in plasma within the time limit of 5 minutes, with volume limit of 20 microliters and with dilution ratio limit of 10):

$$tvd.score = \left(\frac{300 - time}{300} + \frac{20 - volume}{20} + \frac{10 - dilution\ ratio}{10}\right)$$

After the *tvd.score* is calculated, accuracy will be taken into account by applying the following formula to obtain the *accuracy weighted score* for each measurement.

$$accuracy\ weighted\ score = f(tvd.score) = \begin{cases} 1 \times tvd.score, & error\ 0\% \leq 20\% \\ 0.8 \times tvd.score, & error\ 20\% \leq 40\% \\ 0.6 \times tvd.score, & error\ 40\% \leq 60\% \\ 0.4 \times tvd.score, & error\ 60\% \leq 80\% \\ 0.2 \times tvd.score, & error\ 80\% \leq 100\% \\ 0 \times tvd.score, & error > 100\% \end{cases}$$

The *accuracy weighted scores* for each point will be added together to obtain a final score.

The theoretical maximum *tvd.score* for each point is 3. This means the maximum final (total) score that can be obtained is 3x the total number of samples.

Please Note: the above algorithm is still subject to change, especially the weightings of various components.

Creativity Award

The Creativity award expresses appreciation for the team that has been most surprising and thereby sets a new standard for the upcoming years. Examples are given below, however, these are not constraints. The award is based on judgment on the originality and novelty of the technical solution, but also on how it was realized (the process):

1. Technological aspects weight 70%

The creativity demonstrated by the team in the technological concepts of the biosensor. This can involve the components (e.g. biomaterials, detection principle, cartridge concepts, readout method, signal processing, manufacturing or assembly methods) as well as the combination and integration of components and the total system design.

2. Process weight 30%

The creativity demonstrated in how the team came to their solutions. Did the team develop surprising and effective ways to work as a team, to work with companies and sponsors, to work with healthcare professionals and the general public, etc.