

Corporate Staff

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Customers of Diagnostic Services

Date	June 21 2018	Of	C. Hoyer
Our reference	1806-0228 v1.0	Title	Privacy Officer
Subject	Sanquin Diagnostic Services as controller	Department	Corporate staff

Dear Mr, Mrs,

The essence of being of a data controller is that a data controller determines 'the purpose and means' with respect to the processing of personal data. A data processor solely processes personal data on behalf of the data controller.

It is evident that the purpose for processing personal data is substantially determined by a health care provider (*Customer*), namely the analysis of a sample to determine the inclusion or exclusion of that sample based on a probability or differential diagnosis. A medical laboratory (such as Sanquin) has however considerable professional autonomy when executing any analysis and dealing with ancillary data.

As being required for each accredited medical laboratory that processes personal data and analyses samples, Sanquin Diagnostiek is subject to the NEN-ISO 15189 Standard. This Standard sets high thresholds with respect to the processing of received personal data, the usage of the results of an analysis of samples and the reporting requirements to the customer (according to the NEN-ISO 15189 Standard).

A medical laboratory needs to store and have available the results during a statutory retention period and needs to have a (quality) monitoring system at its disposal to compare the outcome of the analysis. This to ensure that the laboratory can provide a Customer with a complete report.

The Standard assumes that a Customer is not able to determine the content of the report. The medical laboratory has its own discretionary professional responsibility. Any analysis of a sample generates new data of which the substance is determined in full by the professional expertise of the medical laboratory.

In addition thereto, the laboratory determines how the samples need to be collected in terms of the Standard and which data are required to ensure a proper analysis. Any Samples not complying with the Standard's specifications cannot be analyzed. In general this has been laid down in the applicable professional standards, such as the NEN-ISO 15189 Standard.

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Although not necessarily top of mind, this means that any medical laboratory de facto determines the means required to achieve the purpose of a Customer.

This leads to the conclusion that a Customer has limited control over the means, marginal control over the purpose and no control over the outcome of the provided personal data and analysis of the sample.

The medical laboratory has, based on amongst others the NEN-ISO 15189 Standard, such a substantial own professional responsibility that it's role has to be seen as a data controller. Aforementioned requires Sanquin to put in place agreements with all Customers regarding the processing of personal data, being from data controller to data controller

A data processing agreement from data controller to processor cannot be agreed upon, since Sanquin Diagnostiek is to be considered a data controller regarding aforementioned processing of personal data and not a processor. Sanquin Diagnostiek however fully acknowledges the need to contractually arrange the various aspects of exchanging personal data between both parties.

Kind regards,

A handwritten signature in black ink, appearing to be 'C. Hoyer', with a long horizontal line extending to the right.

Mr. C. Hoyer
Privacy Officer