

2013-133

EINSCHREIBEN

Swiss Stem Cells Bank SA
Dr. Veronica Albertini
Scientific Director
Via ai Söi 24
6807 Taverne

Berne, 4 April 2014

Inspection, Reference-Nr.: 2013-133; BAG Nr.: IS2013-nTxZ101-N0-V00 et IS2013-nTxZ102-N0-V00

Dear Dr. Albertini

We would like to again thank you and your colleagues for your hospitality and the competent collaboration during the inspection dating 22 January 2014. Please find enclosed the inspection report.

Please submit to Swissmedic an action plan addressing the deviations listed in chapter C of the report until **4 May 2014**. If you have any questions do not hesitate to contact us.

Yours sincerely

Swissmedic
Section Authorizations
Inspector



Dr. Martin Burgener

Copie:

- Federal office of public health

Licensing Sector
Inspectorates Division
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3000 Bern 9
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Inspection report

Name of establishment: Swiss Stem Cell Bank
Taverne

Date of inspection: 22 January 2014

A. Information

A.1 Information for the inspection

Company address	Swiss Stem Cell Bank SA Via ai Söi 24 6807 Taverne
Establishment licence	none
Date of inspection	22 January 2014
Swissmedic inspection team	Dr. Martin Burgener
Participants from the company	Dr. Veronica Albertini, Cord Blood Bank Director Mrs. Patrizia Franconi, CEO Mrs. Anna Serra, Quality Manager Supervisor Mr. Fabio Frasnelli, Administrative Mr. Stefano Panella, Laboratory Technician Mrs. Anna Tortora, Laboratory Technician Mr. Gennaro Tortora, Administrative Luciano Gilardoni, Administrative
Other participants	none
Purpose of the inspection	The inspection took place within the framework of a mandated inspection on behalf of the federal office of public health.
Scope of the inspection	<ul style="list-style-type: none"> - General organisation and collaboration with third parties - Quality assurance system (SOPs, training of personnel, deviation management, change control etc.) - Written agreements with parents - Training of personnel performing the procurement - Preparation of Cord Blood unit and analytical methods - Validation of processes - Premises and equipment - Validation, Qualification, Maintenance, Calibration - Storage and transport - Traceability and Biovigilance
Last Inspection	For this site so far no inspection has been performed. For the former site in Lugano the inspection 2010-029 has been conducted .

<p>Legal basis</p>	<ul style="list-style-type: none"> - Law on Transplants (SR 810.21) - Ordinance on Transplants (SR 810.211) - Guide to safety and quality assurance for the transplantation of organs, tissues and cells, Council of Europe Publishing - NETCORD/FACT Standards (International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release, Foundation for the Accreditation of Cellular Therapy) - EU Guideline for Good Manufacturing Practices, human medicines (94/C 63/03) - Frame contract between the Federal Office of Public Health and Swissmedic - Modul contract between the Federal Office of Public Health and Swissmedic regarding the enforcement and other supporting task in the field of transplant medicine - Federal Office of Public Health mandate to inspect, mandate nr.: IS2013-nTxZ101-N0-V00
<p>Other basic documents</p>	<ul style="list-style-type: none"> - Quality Manual

A.2 Description of the Company

The Swiss Stem Cell Bank SA (SSCB) runs in Taverne a blood stem cell bank for the storage of autologous cord blood units (CBU). The SSCB was formerly seated in Lugano and has moved in July 2013 to Taverne.

SSCB is responsible for the acquisition of new clients, importing CBU from abroad, processing and storage of CBU. In 2013 about 900 CBU were processed and stored.

SSCB is processing and storing on a contract manufacturer basis CBU's for Procrea stem cells SA.

SSCB is since 2012 accredited according to the NECTCORD guidelines.

SSCB has future plan to process and store autologous stromal vascular fraction for homologous use (i.e. Lipofilling).