International Federation of Clinical Chemistry and Laboratory Medicine
Working Group "Laboratory Errors and Patient Safety"

MODEL OF QUALITY INDICATORS FOR GENETIC DIAGNOSIS

The following Quality Indicators have been proposed by Prof. Wang Qingtao (Beijing CCL Director) and Drs. Zhou Rui (Beijing CCL- Lab Manager) and aim the performance improvement in Genetic Diagnosis.

KEY PROCESSES SPECIFIC QUALITY INDICATORS – PRIORITY 1					
Quality Indicator	**Code**	**Reporting Systems**	**Data Collection**	**Time**	**Explanatory Note**
INTRA-ANALYTICAL					
DNA extraction success rate	Intra-DNA Ext	Number of one time successfully extracted samples/total number of samples;	a) count number of one time successfully extracted samples b) count total number of samples extracted c) calculate percentage	Data collection: Every day Input data: Monthly	DNA extraction success = extracted samples which pass internal extraction QC
Library QC success rate	Intra-Lib	Number of one time library pass QC/total number of library	a) count number of one time library pass QC b) count total number of library c) calculate percentage	Data collection: Every day Input data: Monthly	Library QC success = libraries which pass internal library preparation QC
Sequencing success rate	Intra-Seq	Number of one time library sequenced successfully samples / total number of sequencing samples	a) count number of one time library sequenced successfully b) count total number of library c) Calculate percentage	Data collection: Every day Input data: Monthly	Sequencing success = libraries which pass internal sequencing QC
Date analysis success rate	Intra-Dat	Number of one time successfully analysed samples / total number of analysis samples	a) count number of one time successfully analysed samples b) count total number of samples analysed c) calculate percentage	Data collection: Every day Input data: Monthly	Date analysis success = samples which pass internal data analysis QC
POST-ANALYTICAL					
Report error rate	Post-Err	Number of rectified reports by laboratory after the release / total number of released reports	a) count number of rectified reports by laboratory after the release b) count total number of released reports c) calculate the percentage	Data collection: Every day Input data: Monthly	Rectified reports include inappropriate/ missed interpretative comments or wrong patient's details
Report delay rate	Post-Del	Number of delayed reports/ total number of reports	a) count number of delayed reports b) count total number of reports c) calculate percentage	Data collection: Every day Input data: Monthly	Delayed reports = reports which are over the TAT committed by laboratory TAT=from sample reception by laboratory to release of result;

KEY PROCESSES SPECIFIC QUALITY INDICATORS – PRIORITY 3					
Quality Indicator	**Code**	**Reporting Systems**	**Data Collection**	**Time**	**Explanatory Note**
The positive rate of EGFR- lung cancer	Post-Rate-EGFRLu	Accumulate EGFR mutations of lung cancer samples/Accumulate lung cancer samples	a) accumulate number of EGFR mutations of lung cancer samples b) accumulate total number of lung cancer samples c) calculate the percentage	Data collection: Monthly Input data: Accumulate samples taken before the statistical time	The detection rate of EGFR gene in lung cancer
The positive rate of BRAF-melanoma	Post-Rate-BRAFMe	Accumulate of BRAF mutations in melanoma samples/Accumulate melanoma samples	a) accumulate number of BRAF mutations in melanoma samples b) accumulate total number of melanoma samples c) calculate the percentage	Data collection: Monthly Input data: Accumulate samples taken before the statistical time	The detection rate of BRAF gene in melanoma
The positive rate of RAS-colorectal cancer	Post-Rate-KRASClo	Accumulate KRAS mutations of colorectal cancer samples/Accumulate colorectal cancer samples	a) accumulate number of KRAS mutations of colorectal cancer samples b) accumulate total number of colorectal cancer samples c) calculate the percentage	Data collection: Monthly Input data: Accumulate samples taken before the statistical time	The detection rate of KRAS gene in colorectal cancer
The positive rate of ALK fusion-lung cancer	PosT-Rate-ALKLun	Accumulate ALK fusion of lung cancer samples/Accumulate lung cancer samples	a) accumulate number of ALK fusion of lung cancer samples; b) accumulate total number of lung cancer samples c) calculate the percentage	Data collection: Monthly Input data: Accumulate samples taken before the statistical time	The detection rate of ALK fusion gene in lung cancer
The positive rate of ROS1 fusion-lung cancer	Post-Rate-ROS1Lun	Accumulate ROS1 fusion of lung cancer samples/Accumulate lung cancer samples	a) accumulate number of ROS1 fusion of lung cancer samples b) accumulate total number of lung cancer samples c) calculate the percentage	Data collection: Monthly Input data: Accumulate samples taken before the statistical time	The detection rate of ROS1 fusion gene in lung cancer
The positive rate of IDH1/IDH2 /TERT-glioma	Post-Rate-IDH/TERTGl	Accumulate IDH1/IDH2/TERT mutations of glioma samples/Accumulate glioma samples	a) accumulate number of IDH1/IDH2/TERT mutations of glioma samples b) accumulate total number of glioma samples; c) calculate the percentage	Data collection: Monthly Input data: Accumulate samples taken before the statistical time	The detection rate of IDH1 / IDH2 / TERT gene in glioma
The positive rate of Her2 amplification – breast cancer	Post-Rate-Her2Bre	Accumulate Her2 mutations of breast cancer samples/Accumulate breast cancer samples	a) accumulate number of Her2 mutations of breast cancer samples b) accumulate total number of breast cancer samples c) calculate the percentage	Data collection: Monthly Input data: Accumulate samples taken before the statistical time	The detection rate of Her2 gene in breast cancer