deviation record

# Deviation Record

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| Study Number | | A2018030-BA01 |
| Study Director | | Xu Zhenxing |
| Type of deviation  Deviation Category | Protocol Deviation □ SOP Deviation | |
| Deviation Description  Description of the deviation | According to the assay schedule: the verification time for assay sample reanalysis is between 2018-12-19 and 2018-12-25; the verification time for plasma sample long-term cryopreserved stability and stock solution stability is between 2018-12-26 and 2019-01-02.  During the actual operation, the verification of the assay sample reanalysis was performed on 2019-01-01; the verification of the plasma sample long-term cryopreserved stability and stock solution stability was performed on 2019-01-10. This does not match the assay schedule.  Signature： Date： | |
| Corrective Action(s) and Evaluation  Handling of Deviations measures and evaluation | Record this deviation truthfully.  This deviation is an assay schedule deviation. The duration of the plasma sample long-term cryopreserved stability and stock solution stability is greater than the time specified in the assay schedule. Moreover, the duration of the plasma sample long-term cryopreserved stability can cover the actual cryopreserved time of the blood sample, so this deviation does not affect the scientific validity of the assay.  Signature： Date： | |
| Remark Notes: If the deviation is outside the range of ability of the SD/PI or department director to evaluate or resolve, it must be reported to the QAU and Test Facility Management. If the SD/PI or department director is not able to evaluate deviations, it must be reported to QAU and TFM. | | |