

Blood Cell Storage, Inc. (BCSI) 4203 23<sup>rd</sup> Ave W Seattle, WA 98199

# CSMP – Field Advisory Notice (FAN)

Variable sv<sup>2</sup> sensor performance in Lot 2105035

070622SV20027

## **Identified Issue**

 $sv^2$  sensors from production lot 2105035 (pHID 85YIR) have been identified as having variable pH performance. Some  $sv^2$  sensors in the lot read pHs as expected while others can read the pH as lower than expected.

### Analysis

Variability was observed in the  $sv^2$  sensor pH performance. It is not possible to identify the  $sv^2$  sensor's pH differences prior to use.

### Impact to Owners

If pH tests were run with the  $sv^2$  sensors from lot 2105035, please consider the pH results suspect. In some cases, the reported pHs will be lower than actual pH levels.

### Procedure

The  $sv^2$  sensor kits from production lot 2105035 will be replaced with new kits. Owners should not use the sensors they have, and should request replacements from sales contacts or SAFE Sens directly at <u>support@safesens.com</u>.

Please contact me should you require additional information. Thank you for your continued interest in the SAFE Sens products.

Steve Geelhood Business Director Blood Cell Storage, Inc. support@safesens.com 08-June-2022

Date

Transmittal & receipt acknowledged by CSMP