Carter BloodCare

Date: August 26, 2016

To: Transfusion Facilities

From: Hospital Relations

Subject: Updated FDA Guidance for Zika testing

The FDA updated guidelines today concerning donor screening for Zika virus infection. The agency requires that all donations collected in the United States be tested by individual donor nucleic acid test.

For Southern states, which include Texas, testing must be implemented within 4 weeks.

With regards to testing, Carter BloodCare has an advantage in that a nationally renowned laboratory, Creative Testing Solutions, is on our premises and has had extensive experience, elsewhere in the country, with the research test for Zika screening in donors.

It is important to emphasize, during the period of time that Carter BloodCare ramps up for testing, that there have been no locally reported mosquito transmissions of Zika and the blood program in Houston found no positive donors in 50,000 tested.

Please note that the updated guidelines do **NOT** indicate the need for hospitals to alter their patient blood consent for high risk patients, namely pregnant women and fetuses in utero, to address the IND testing.

The guidance is attached for your reference.