

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) <small>(See reverse side for instructions)</small>		1. REGISTRATION NUMBER <small>(FDA Establishment Identifier)</small> FEI: 3012085771	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:19-NOV-2016 DISTRICT: Cincinnati PRINTED BY FDA:15-DEC-2016	
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PART I - ESTABLISHMENT INFORMATION 3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		PART II - PRODUCT INFORMATION 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th rowspan="2" style="width:20%;">Types of HCT / Ps</th> <th colspan="8" style="text-align: center;">Establishment Functions</th> <th rowspan="2" style="width:3%;">11. HCT/PS DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2" style="width:3%;">12. HCT/PS REGULATED AS MEDICAL DEVICES</th> <th rowspan="2" style="width:3%;">13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS</th> <th rowspan="2" style="width:15%;">14. PROPRIETARY NAME(S)</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> </tr> <tr><td>a. 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4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) AxoGen Corporation 349 South Main Street 4th Floor Dayton, Ohio 45402 a. PHONE 3864626800 EXT 6820 b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		5. ENTER CORRECTIONS TO ITEM 4 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) AxoGen Corporation Attn: Mark L. Friedman, Ph.D. 13631 Progress Blvd Suite 400 Alachua, Florida 32615 a. PHONE 3864626800 EXT 6820																																																																																																																																																																																																																																																																																																																												
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9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Mark L. Friedman, Ph.D. b. E-MAIL mfriedman@axogeninc.com c. TITLE VP of RA & QA d. DATE 18-NOV-2016																																																																																																																																																																																																																																																																																																																														