MAGBIO
"WE MAKE NGS BETTER"

MagBio Genomics, Inc. Quality Self-Assessment

Management Review	Y	N
Does the management team of the organization review product performance data and corporate performance data? Are findings from these reviews documented and used to modify processes within the organization?	x	
Document/Record Control	**Y**	**N**
Does the organization have a method for control of work procedures?	x	
Does the organization have a method for controlling records? This includes records of work processes, records of equipment calibration, product testing results, etc.	x	
Does the organization have a method to ensure that obsolete procedures are not mistakenly used?	x	
Does the organization ensure that documents and records are available at the point of use?	x	
Human Resources	**Y**	**N**
Does the organization hired and trained personnel to ensure that their knowledge is adequate to perform processes? Does the organization document employee training?	x	
Does the organization document health and safety instructions, including instructions for use of personal protective equipment?	x	
Work Environment	**Y**	**N**
Does the organization ensure that infrastructure is maintained in its facility?	x	
Does the organization have methods for controlling areas for product handling? This includes control of contamination and cleanliness.	x	
Research and Development	**Y**	**N**
Does the organization have a process for designing and developing new products? Is	x	

this process recorded?		
Does the organization have a process for designing and developing products that were initially designed elsewhere? Is this process recorded?	x	
Does the organization have a process for documenting changes to processes and ensuring that the changes will not negatively impact product performance? Is this process recorded?	x	
Does the organization notify customers of product changes that may impact product functionality?	x	
Production and Material Handling	**Y**	**N**
Does the organization assess and reassess its suppliers and subcontractors?	x	
Does the organization ensure that incoming materials inspected and assessed before use?	x	
Does the organization control and document production processes?	x	
Does the organization document the validation of physical processes, equipment, and software, ensuring that they are adequate for use?	x	
Does the organization ensure that products and materials are identifiable and traceable throughout the process of receiving, manufacturing, sale to customers? Does the organization have processes to ensure that materials are stored and used under suitable conditions?	x	
Does the organization control instrument calibration? Is an instrument marked when it is in need of calibration and cannot be used?	x	
Does the organization ensure that equipment for monitoring and measuring is functioning properly?	x	
Does the organization ensure that data produced during product testing is analyzed consistently? Is data analysis documented?	x	

Does the organization document packaging and shipping processes? Does the organization ensure that packaging is done in a way that protects products from damage and deterioration during shipping?	x	
Nonconformity	**Y**	**N**
Does the organization record and respond to customer feedback, including customer complaints?	x	
Does the organization have a procedure to determine whether making a report to regulatory authorities is necessary?	x	
Does the organization identify and control nonconforming product, ensuring that it is not used improperly after a nonconformity is identified?	x	
Does the organization have processes for reworking product that is found to be nonconforming?	x	
Does the organization ensure that process changes are made to correct issues that have already occurred, and prevent issues from reoccurring? Are these process changes documented?	x	
Does the organization initiate process changes when a potential issue is observed? Are these process changes documented?	x	
After process changes are implemented to correct or prevent an incident, does the organization follow up to ensure that the changes effectively addressed the issue and did not have negative effects?	x	