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DEVELOPMENT OF ANTIBODY DETECTION METHODS FOR ACTIVE PRODUCT AT THE CELL CULTURE STAGE

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Development of new analytical methods to characterize the manufacturing process became necessary when the site wanted to implement process improvements to increase output from the bioreactor. The bioreactor process is monitored and controlled for dissolved oxygen content, glucose concentration, temperature, etc. and samples of the harvest are analyzed daily using an endpoint assay and a total protein method. Neither of the two methods can detect the total amount of product at the harvest stage; the endpoint assay will only detect active product and the total protein method will not discriminate between the cellular proteins and the active product. We have developed antibody based methods to overcome these challenges.