

## IVD\_10 - Scale up of molecular kit for diagnostic of COVID-19 during pandemic period

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**Introduction:** Scale up from laboratorial development phase of a molecular kit for COVID-19 diagnosis following the protocols preconized from WHO to detection of molecular targets of SARS-COV-2. The production method for industrial scale was established to reach 500.000 reactions per week in three weeks, starting from 30.000 reactions per week, offering a new product in Bio-Manguinhos portfolio, and attending the needs of Ministry of Health , helping to face the pandemic situation emergency.

**Objective:** Scale up the molecular kits for COVID-19 Diagnosis, from 30.000 reaction per week to 500.000 reaction per week.

**Methodology:** Based on chrono analysis to evaluate the processing time and movements of production activities. Processing times, number of components of the kits, parameters restrictions, was possible design the model of operations into the production area. It was possible, as well, to evaluate head count, team organization and training of the team, coordinating actions of logistic, development and production to reach the main goal.

**Results:** It was accomplished the planning to contract personnel gradually, in order to evaluate the efficiency of training and performance of the team. Besides that, it was important the planning and organization of raw material acquisition and delivery at Bio-Manguinhos site. Regulatory and good manufacturing practices for *in vitro* diagnosis were necessary to implement this production. The period was comprehended from April, 12 to May 02, when 500.000 reaction/week was reached in one shift during 44h weekly.

**Conclusion:** The process design was well succeeded, the schedule was fully followed, with reaction delivered to the MOH in time agreed.

**Keywords:** Covid-19; Process scale up; SARS-COV-2